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The contents of the Journal are indexed in Hospital and Health Administration Index, Cumulative Index to Nursing and Allied Health Literature, and Excerpta Medica. Abridged versions of RESPIRATORY CARE are also published in Italian and Japanese, with permission from Daedalus Enterprises Inc.
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Editorials, Commentaries, and Reviews To Note

The Initiation or Withdrawal of Treatment for High-Risk Newborns (Statement)—American Academy of Pediatrics Committee on Fetus and Newborn. Pediatrics 1995;96(2):362-363.

Drug-Exposed Infants (Statement)—American Academy on Pediatrics Committee on Substance Abuse. Pediatrics 1995;96(2):364-367.

***ß*-Adrenergic Bronchodilators** (Review)—HS Nelson. N Engl J Med 1995;333(8): 499-506.

Several papers from *JAMA*, the *New England Journal of Medicine* and the *Lancet* may be of particular value to those interested in the debate between the tobacco industry and health-care providers and the issues of smoking cessation and prevention.

The Brown and Williamson Documents: The Company's Response—T Graham. JAMA 1995;274(3):254.

Looking Through A Keyhole at the Tobacco Industry—SA Glantz, DE Barnes, L Bero, P Hanauer, J Slade. JAMA 1995;274(3):219.

Nicotine and Addiction—J Slade, LA Bero, P Hanauer, DE Barnes, SA Glantz. JAMA 1995; 274(3):225.

Lawyer Control of Internal Scientific Research To Protect Against Products Liability Lawsuits—P Hanauer, J Slade, DE Barnes, L Bero, SA Glantz. JAMA 1995;274(3):234.

Lawyer Control of the Tobacco Industry's External Research Program—L Bero, DE Barnes, P Hanauer, J Slade, SA Glantz. JAMA 1995;274 (3):241.

Environmental Tobacco Smoke—DE Barnes, P Hanauer, J Slade, LA Bero, SA Glantz. JAMA 1995;274(3):248.

Determinants of Compliance with a National Smoke-Free Hospital Standard—AM Joseph, JM Knapp, KL Nichol, PL Pirie. JAMA 1995;274 (6):491. *See the related editorial:* ***Smoke-Free 2000: A Step Closer****—TE Kottke. JAMA 1995;274 (6)503-504.*

Smoking Bans in US Hospitals: Results of a National Survey—DR Longo, RC Brownson, RL Kruse. JAMA 1995;274(6):488. *See the related editorial:* ***Smoke-Free 2000: A Step Closer****—TE Kottke. JAMA 1995;274(6)503-504.*

Sounding Board: Nicotine Addiction in Young People—DA Kessler. N Engl J Med 1995; 333(3):187-188.

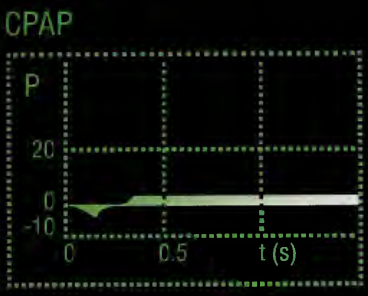
Objective Passive-Smoking Indicators and Respiratory Morbidity in Young Children—CG Bakoula, YJ Kafritsa, GD Kavadias, DD Lazopoulou, MC Theodoridou, KP Maravelias, NS Matsaniotis. Lancet 1995;346:280.

Neonatal Technology, Perinatal Survival, Social Consequences, and the Perinatal Paradox—RM Kliegman. Am J Public Health. 1995;85 (7):909.

Exogenous surfactant therapy for premature infants with respiratory distress syndrome has had a significant impact on infant mortality and on some complications of prematurity. Yet the total number of low-birthweight infants has not declined, resulting in a high-risk population who would require surfactant therapy and long-term child care. Surviving low-birthweight infants (despite surfactant therapy) remain at risk for the consequences of premature birth, such as neurosensory impairment, cerebral palsy, and chronic lung disease. In addition, because of the close association between poverty and low birthweight, surviving premature infants are at increased risk for the new morbidities such as violence, homelessness, child abuse and neglect, and addictive drug use. A goal should be to reduce the risk of being born with a low birthweight, rather than having to treat the consequences of premature gestation. Despite the marvelous advances that permit us to treat respiratory distress syndrome, the continuing high low-birthweight rate places a significant strain on our health-care system. The goal should be redirected to identifying large population-based efforts to reduce the number of low-birthweight infants. *See the related editorial:* ***The Perinatal Paradox****—A Leviton. 1995;85(7):906-907.*

Infant Sleep Position Following New AAP Guidelines—E Gibson, JA Cullen, S Spinner, K Rankin, AR Spitzer. Pediatrics 1995;96(1):69.

OBJECTIVE: This report examines the response of families to the American Academy of Pediatrics June 1992 recommendation that healthy term infants be put to sleep on their back or side to decrease the risk of sudden infant death syndrome. Parents at two clinics and private practices were interviewed to ascertain sleep position practices. METHODS: Parents of infants from 1 to 6 months of age who were in the waiting room for a well-child visit were eligible for study. A total of 760 interviews were conducted using a closed-ended questionnaire. Parents were asked about sleep position, positional changes during sleep, and factors that influenced their decision to position their infant prone, side, or supine. Interviews were conducted from September 1993 through April 1994. This interval was divided into two equal, 4-month time intervals. Sleep practices were compared during the first and second time periods. Differences between practice and clinic groups were measured. Groups were compared using the chi-square test, with results considered significant at $p < 0.05$. RESULTS: The number of infants placed side or supine for sleep increased significantly since the inception of the study, from 38.1% to 59.1%. Despite this increase, parents reported that the impetus for changing position came from family or the media, rather than from health professionals. Initially, the proportion of infants in private practices placed side or supine was greater than that of clinic patients. That difference disappeared by the end of the study. Prone positioning continued to be more prevalent in the 3- to 6-month-old in-



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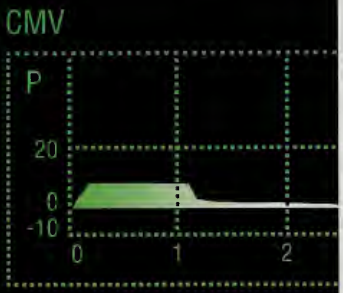

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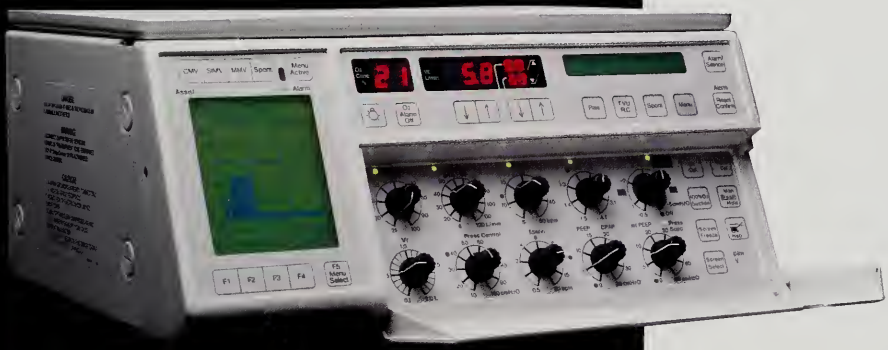

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fants than in the 1- to 3-month-old group. The majority of infants at all ages awoke in the same position that they were put to sleep. CONCLUSIONS: Side and supine positioning for sleep increased in all socioeconomic groups. A small number of infants placed side or supine for sleep are found prone on awakening. Health professionals need to increase their role in providing sleep position guidance. As the proportion of the population positioning their infants side or supine for sleep increases, it should be possible to examine the effect on the sudden infant death syndrome rate.

Aerosolized Furosemide in Wheezy Infants: A Negative Report—HP Van Bever, KN Desager, JH Pauwels, M Wojciechowski, PA Vermeire. Pediatr Pulmonol 1995;20(1):16.

We investigated the effects of 10 mg aerosolized furosemide on clinical score in 28 acutely wheezing infants (Part A) and in a second group of 20 intermittently wheezing babies on airway resistance and functional residual capacity during a symptom-free period (Part B), using a double-blind, placebo-controlled design. In both parts of the study no therapeutic effects were observed during and following aerosol inhalation of 10 mg furosemide.

Inspiratory Fall in Systolic Pressure in Normal and Asthmatic Subjects—MD Goldman, M Mathieu, JM Montely, R Goldberg, JM Fry, JL Bernard, R Sartene. Am J Respir Crit Care Med 1995;151:743.

We used a noninvasive monitor of arterial pressure to determine whether respiratory changes in arterial pressure were closely correlated with airflow obstruction in asthmatic patients during bronchial challenge with methacholine. To validate the noninvasive measurement of respiratory changes in arterial pressure, a preliminary study in 6 subjects with normal cardiovascular and respiratory systems was done during cardiac catheterization for suspected coronary artery disease. There were no significant differences between inspiratory falls in systolic pressure measured noninvasively and those measured from intra-aortic pressure. In 11 otherwise healthy asthmatic patients we measured finger arterial pressure, end-expiratory lung volume (FRC), and forced expired volume (FEV_1) during baseline and bronchial challenge in the supine posture. Finger arterial pressure was also measured in 11 normal control subjects seated and supine. Normal subjects had an inspiratory fall in systolic pressure (IFSP) of 3.2 mm Hg supine and 5.1 mm Hg seated ($p < 0.01$). Asthmatic patients when bronchodilated (seated $FEV_1 = 83 \pm 7\%$ of predicted) had an IFSP of 5.9 mm Hg supine ($p < 0.01$ compared with supine normal subjects). During bronchial challenge (average fall in $FEV_1 = 22\%$), IFSP increased to 16.1 mm Hg ($p < 0.001$ compared with baseline). In asthmatic subjects, there was a significant correlation between IFSP and FEV_1 (mean $r = -0.92 \pm 0.05$, $p < 0.01$), and the average change in IFSP/change in FEV_1 was –0.38 mm Hg per percentage change in FEV_1. During subsequent bronchodilation, IFSP decreased with a similar time course as relaxation of airway smooth muscle, assessed by the breath-to-breath fall in FRC. We conclude that measurement of IFSP from finger arterial pressure is a useful index of clinical state in asthmatic patients during moderate bronchoconstriction. The method is sensitive enough to detect differences between normal and bronchodilated asthmatic subjects and differences in normal subjects between upright and supine.

Effect of Inspiratory Flow Rate on Respiratory Sensation and Pattern of Breathing—HL Manning, EJ Molinary, JC Leiter. Am J Respir Crit Care Med 1995;151:751.

We examined the effect of inspiratory flow rate (IFR) on respiratory sensation during mechanical ventilation in 10 normal subjects. We adjusted the ventilator tidal volume (V_T), frequency, and IFR until subjects indicated that they were maximally comfortable ("comfort IFR"). Subjects then rated breathing discomfort on a visual analog scale (VAS) while IFR was varied among four levels: 70%, 100%, 200%, and 300% of the comfort IFR. When compared with VAS ratings at the comfort IFR (4.4 ± 1.2, mean ± SEM), VAS ratings were significantly greater at the lowest (ie, 70% comfort; 12.1 ± 2.1) and highest (300% comfort; 8.2 ± 0.9) IFR; there was no difference in ratings between the comfort IFR and 200% comfort IFR. At the lowest IFR, the breathing discomfort arose in the chest and had an air hunger-like quality; at high IFR, the discomfort arose in the upper airway. In the second portion of the study, subjects used open magnitude estimation to rate breaths of five different sizes at three different IFR (70%, 100%, and 200% of comfort rate). Neither the exponent nor intercept for V_T perception differed among the three IFR. Our results demonstrate that although IFR does not alter magnitude estimation of breath size, deviations of IFR from that desired by the subject may greatly affect respiratory comfort.

Normal Sweat Chloride Values Do Not Exclude the Diagnosis of Cystic Fibrosis—B Stewart, J Zabner, AP Shuber, MJ Welsh, PB McCray Jr. Am J Respir Crit Care Med 1995;151:899.

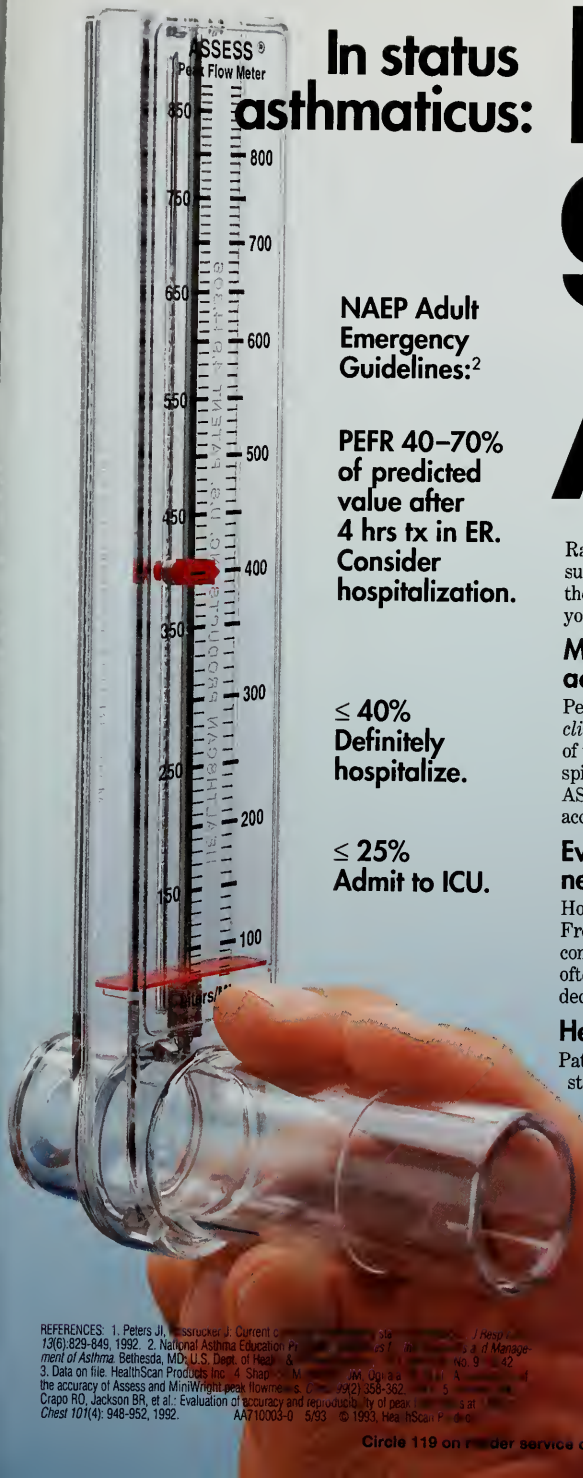
Since its introduction in 1959, the sweat test has remained the "gold standard" diagnostic test for cystic fibrosis (CF). It is apparent that CF encompasses a wide spectrum of disease, from meconium ileus and severe respiratory compromise in infants to the presentation of mild pulmonary symptoms and no evidence of gastrointestinal disease in adults. In patients with lung disease that might otherwise be consistent with CF, normal sweat chloride (Cl^-) values have tended to exclude the diagnosis. In this report we describe two patients from two families with the compound heterozygotic CF mutations ΔF508/3849 + 10 kb C→T. These patients had mild manifestations of disease, including clinical pancreatic sufficiency (normal growth without pancreatic enzyme supplementation) and absence of azoospermia. Sweat Cl^- values were in the normal range. However, both patients developed bronchiectasis, progressive obstructive lung disease, and colonization with Pseudomonas. The diagnosis of CF was made using nasal transepithelial voltage measurements and genotyping. These cases emphasize the need to maintain a high index of suspicion of CF in atypical cases, and to pursue alternative diagnostic tests to confirm a diagnosis of CF suspected on clinical grounds, despite normal sweat test results.

Sensitivity and Specificity of Oropharyngeal Suction Versus Bronchoalveolar Lavage in Identifying Respiratory Tract Pathogens in Children with Chronic Pulmonary Infection—A Avital, K Uwyyed, E Picard, S Godfrey, C Springer. Pediatr Pulmonol 1995;20(1):40.

The purpose of this study was to compare the pathogens obtained by oropharyngeal suction (OPS) and bronchoalveolar lavage (BAL) in children with chronic pulmonary infections Forty-four children (mean age of 6.1 years; range 4 months to 15 years) were included in the study (27 children with recurrent localized lung infection, 5 with bronchiectasis, 5 with cystic fibrosis, 2 with foreign body aspiration, 2 with bronchiolitis obliterans, and 3 children with recurrent episodes of cough and shortness of breath). In 27 out of 44 BAL samples (61%) bacterial cultures were positive. The sensitivity of OPS in detecting the same BAL pathogen was 89% (24/27 samples), the specificity was 94% (16/17 samples), and the predictive value was 91% (40/44 samples). *Hemophilus influenzae* β-lactamase negative was the main organism recovered from BAL in non-cystic fibrosis patients with recurrent or persistent pneumonia. We conclude that OPS is a simple and efficient noninvasive procedure which may be helpful in the diagnosis and treatment of recurrent or chronic pulmonary infection.

SP-A Deficiency in Primate Model of Bronchopulmonary Dysplasia with Infection: *In Situ* mRNA and Immunostains—JJ Coalson, RJ King, F Yang, V Winter, JA Whitsett, RA Delemos, SR Seidner. Am J Respir Crit Care Med 1995;151:854.

The surfactant protein secretory cells in airway and alveolar epithelium were studied in premature baboons with bronchopulmonary dysplasia and superimposed infection. PRN animals were delivered by hysterotomy at 140 days gestational age and ventilated on clinically appropriate oxygen for a 16-day experimental period. To assess zero time and sacrifice time gestational parameters, 140 and 156 days were studied. BPD animals were delivered at 140 days and ventilated with positive-pressure



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ventilation and an F_{IO_2} of 1.0 for 11 days followed by 5 days of oxygen sufficient to maintain P_{AO_2} at 40 to 50 mm Hg. BPD-infected animals were comparably ventilated and treated like the BPD group except that 10^8 *E. coli* organisms were endotracheally instilled on Day 11. *In situ* hybridization studies for mRNA expression of SP-A, SP-B, and SP-C revealed that an SP-A mRNA deficiency, present at 140 days, persisted in the BPD and BPD-infected groups, whereas SP-A mRNA was abundant in PRN and 156-day gestation control groups. SP-B and SP-C mRNA expression in the two hyperoxically injured groups was particularly extensive in cells around peribronchiolar and perivascular sites. Immunostaining with SP-A, SP-B, and SP-C antibodies showed variable staining patterns. The study clearly demonstrates that a deficiency of SP-A mRNA expression persists in chronic lung injury and that variable protein staining patterns are manifested depending upon the underlying pathology. *See related editorial:* ***SP-A Deficiency: A Cause or Consequence of Inflammation in Bronchopulmonary Dysplasia?—****JD Crapo, JR Wright. Am J Respir Crit Care Med 1995;151: 595-596.*

Cardiorespiratory Effects of Volume- and Pressure-Controlled Ventilation at Various I/E Ratios in an Acute Lung Injury Model—H Mang, RM Kacmarek, R Ritz, RS Wilson, WP Kimball. Am J Respir Crit Care Med 1995;151:731.

Numerous approaches to the provision of mechanical ventilation during acute lung injury are currently available. Of these, pressure control inverse ratio ventilation has been considered superior to volume control ventilation with PEEP with respect to improving gas exchange and minimizing cardiovascular compromise. However, no study systematically compares volume-controlled (VC) and pressure-controlled (PC) ventilation while maintaining mean airway pressure (MAP) constant at varying I/E ratios. We studied the effect of VC and PC with PEEP at normal (1:2) and inverse I/E ratios (2:1 and 4:1) on gas exchange, lung mechanics, and hemodynamics in a sheep lung injury model. Severe lung injury was induced in 12 sheep with bilateral lung lavages using normal saline; prelavage P_{O_2} 230 ± 50 mm Hg, PEEP 5 cm H_2O and postlavage, pretreatment P_{O_2} 70 ± 20 mm Hg, PEEP 10 cm H_2O, both at F_{IO_2} 0.50. MAP was kept constant throughout the study at 25 ± 2 cm H_2O while ventilating all animals with a V_T of 10 mL/kg and a rate of 20/min by randomized application of VC and PC with I/E ratios of 1:2, 2:1, and 4:1. Despite liberal fluid administration, all ventilatory modes depressed cardiac output compared with preinjury values. However, gas exchange and hemodynamics did not differ among ventilation modes or I/E ratios. Of all the parameters investigated, the most striking changes occurred in peak inspiratory pressure (PIP) and PEEP: PC (I/E 2:1 and 4:1) resulted in significantly ($p < 0.05$) lower values for PIP and applied PEEP compared with control data (VC I/E ratio 1:1), and VC (I/E 4:1) resulted in significantly ($p < 0.05$) lower values for applied PEEP than VC I/E ratio 1:1. Auto PEEP levels during PC (I/E ratio 2:1 and 4:1) and VC (I/E 2:1 and 4:1) were significantly higher ($p < 0.05$) than VC I/E ratio 1:1. When MAP remained constant, alterations in the ventilation mode (PC or VC) or I/E ratio (1:2 to 4:1) produced no significant change in hemodynamic, oxygenation, or ventilation parameters in this sheep model.

Characteristics of Near-Fatal Asthma in Childhood—AJ Martin, DA Campbell, PA Gluyas, JR Coates, RE Ruffin, DM Roder, KM Latimer, CG Luke, PA Frith, PM Yellowlees, G McLennan. Pediatr Pulmonol 1995;20(1):1.

As part of the South Australian asthma mortality survey, we examined 30 cases of near-fatal asthma attacks in children under 15 years of age who were seen over a 3-year period from May 1988 to June 1991. Subjects presented with asthma and either respiratory arrest, P_{aCO_2} above 50 mm Hg, and/or an altered state of consciousness or inability to speak on presentation at a metropolitan Adelaide teaching hospital. A standardized interview and questionnaire were completed with subjects/parents and medical practitioners. Data were reviewed by the assessment panel which made collective judgments based on predetermined criteria. Seventeen patients (57%) were male, 20% were less than 7 years of age, and the majority (53%) were aged between 12 and 15 years. The majority (83%) had severe asthma and only one case (3.3%) had mild asthma. Half of the subjects were waking every night due to asthma and 79% had significant exercise limitation. A quarter of the subjects had a previous ICU admission and 70% had a hospital admission in the last 12 months. Primary care was carried out by a general practitioner in 57% of cases, and 70% of subjects had a crisis plan. Only 46% of those older than 7 years of age had ever used a peak-flow meter. Eighty percent of subjects or their families had high denial scores, and in 73% of cases psychosocial factors were considered to be significant. Eighty percent of cases experienced acute progressive respiratory distress, and 63% of cases delayed seeking medical care. The episode was judged as preventable in 83% of cases. This study suggests that most pediatric cases of near-fatal asthma have severe asthma, significant denial, psychosocial pathology, and delay in seeking care, all of which contribute to the near-fatal nature of these episodes.

The Effect of Inhaled Adrenaline on Lung Function of Recurrently Wheezy Infants Less Than 18 Months Old—AJW Henderson, J Arnott, S Young, T Warshawski, LI Landau, PN LeSouëf. Pediatr Pulmonol 1995;20(1):9.

Inhaled bronchodilators have been shown not to improve lung function in infants with wheeze. This observation has led to the suggestion that airway wall edema may be more important than bronchoconstriction in infants with airway narrowing. Inhaled adrenaline is used to relieve upper airway edema in children with croup and has been demonstrated to improve clinical scores and lower pulmonary resistance in some infants with wheeze associated with bronchiolitis. The aim of the present study was to examine the effect of inhaled adrenaline on lung function in a group of infants with recurrent wheeze. Eleven infants aged 10 to 18 months with a history of recurrent wheeze were studied during an asymptomatic interval. Respiratory function was assessed (1) by measuring maximal expiratory flow at functional residual capacity ($\dot{V}_{max}FRC$) during a forced partial expiratory maneuver and (2) by measuring conductance of the respiratory system (G_{rs}) using a single expiratory occlusion technique. Following baseline measurements, the infants received 0.5 mg/kg adrenaline by nebulizer and serial lung function tests were repeated at 5 min intervals. Ten infants had abnormal baseline lung function (median $\dot{V}_{max}FRC$ 44.2% predicted; median G_{rs} 34% predicted). Using a random effects model, $\dot{V}_{max}FRC$ and G_{rs} declined significantly at 10 and 5 min after adrenaline, respectively. No significant improvements from baseline were observed in either measurement for up to 30 min following adrenaline delivery. It is concluded that inhaled adrenaline did not relieve airways obstruction in this group of asymptomatic infants with recurrent wheeze.

Training Pediatric Residents To Prevent Tobacco Use—JD Klein, M Portilla, A Goldstein, L Leininger. Pediatrics 1995;96(2):326.

OBJECTIVE: To assess the effectiveness and acceptability of incorporating the National Cancer Institute (NCI) *Guide to Preventing Tobacco Use during Childhood and Adolescence* into pediatric training. DESIGN: Pre-intervention and post-intervention self-reported surveys for residents receiving training and postintervention baseline surveys for those residents not receiving training. Measures include: (1) a self-reported knowledge, attitude, and behavior survey of residents; and (2) physician behavior reports from parent exit interviews. SETTING: A hospital-based pediatric residency program and continuity clinic. SUBJECTS: Pediatric residents and parents of pediatric patients seen for well-child examinations. INTERVENTIONS: Structured NCI smoking cessation curriculum modified for delivery during scheduled teaching activities. RESULTS: The NCI training was acceptable and perceived as important by residents. Many did not recall receiving the materials or training. Trained residents who remembered the intervention improved their smoking cessation counseling effectiveness. Most patients' parents think it appropriate for physicians to ask; however, most reported not having been asked about smoking or environmental smoke ex-

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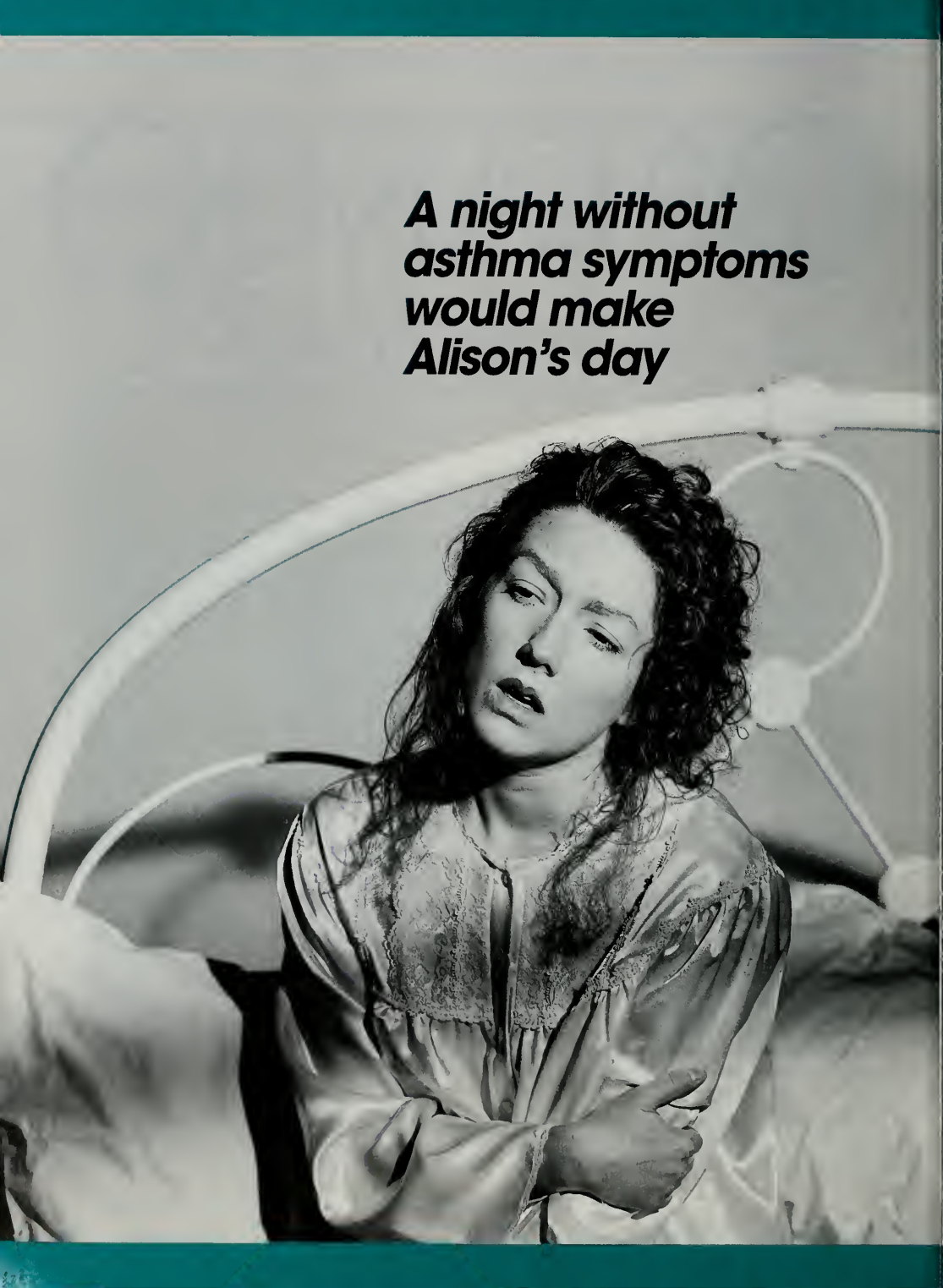
A night without
asthma symptoms
would make
Alison's day

Serevent®
(salmeterol xinafoate)

Serevent® (salmeterol xinafoate) Inhalation Aerosol

BRIEF SUMMARY

Bronchodilator Aerosol
For Oral Inhalation Only

The following is a brief summary only. Before prescribing, see complete prescribing information in Serevent® Inhalation Aerosol product labeling.

CONTRAINDICATIONS: Serevent® Inhalation Aerosol is contraindicated in patients with a history of hypersensitivity to any of the components.

WARNINGS:
IMPORTANT INFORMATION: SEREVENT® INHALATION AEROSOL SHOULD NOT BE INITIATED IN PATIENTS WITH SIGNIFICANTLY WORSENING OR ACUTELY DETERIORATING ASTHMA, WHICH MAY BE A LIFE-THREATENING CONDITION. Serious acute respiratory events, including fatalities, have been reported, both in the US and worldwide, when Serevent Inhalation Aerosol has been initiated in this situation.

Although it is not possible from these reports to determine whether Serevent Inhalation Aerosol contributed to these adverse events or simply failed to relieve the deteriorating asthma, the use of Serevent Inhalation Aerosol in this setting is inappropriate.

SEREVENT INHALATION AEROSOL SHOULD NOT BE USED TO TREAT ACUTE SYMPTOMS. It is crucial to inform patients of this and prescribe a short-acting, inhaled $beta_2$-agonist for this purpose as well as warn them that increasing inhaled $beta_2$-agonist use is a signal of deteriorating asthma.

SEREVENT INHALATION AEROSOL IS NOT A SUBSTITUTE FOR INHALED OR ORAL CORTICOSTEROIDS. Corticosteroids should not be stopped or reduced when Serevent Inhalation Aerosol is initiated.

(See PRECAUTIONS: Information for Patients section of the full prescribing information and the separate PATIENT'S INSTRUCTIONS FOR USE leaflet.)

1. Do Not Introduce Serevent Inhalation Aerosol as a Treatment for Acutely Deteriorating Asthma: Serevent Inhalation Aerosol is intended for the maintenance treatment of asthma (see INDICATIONS and USAGE section of the full prescribing information) and should not be introduced in acutely deteriorating asthma, which is a potentially life-threatening condition. There are no data demonstrating that Serevent Inhalation Aerosol provides greater efficacy than or additional efficacy to short-acting, inhaled $beta_2$-agonists in patients with worsening asthma. Serious acute respiratory events, including fatalities, have been reported, both in the US and worldwide, in patients receiving Serevent Inhalation Aerosol. In most cases, these have occurred in patients with severe asthma (e.g., patients with a history of corticosteroid dependence, low pulmonary function, intubation, mechanical ventilation, frequent hospitalizations, or previous life-threatening acute asthma exacerbations) and/or in some patients in whom asthma has been acutely deteriorating (e.g., unresponsive to usual medications, increasing need for inhaled short-acting $beta_2$-agonists, increasing need for systemic corticosteroids, significant increase in symptoms, recent emergency room visits, sudden or progressive deterioration in pulmonary function). However, they have occurred in a few patients with less severe asthma as well. It was not possible from these reports to determine whether Serevent Inhalation Aerosol contributed to these events or simply failed to relieve the deteriorating asthma.

2. Do Not Use Serevent Inhalation Aerosol to Treat Acute Symptoms: A short-acting, inhaled $beta_2$-agonist, not Serevent Inhalation Aerosol, should be used to relieve acute asthma symptoms. When prescribing Serevent Inhalation Aerosol, the physician must also provide the patient with a short-acting, inhaled $beta_2$-agonist (e.g., albuterol) for treatment of symptoms that occur acutely, despite regular twice daily (morning and evening) use of Serevent Inhalation Aerosol.

When beginning treatment with Serevent Inhalation Aerosol, patients who have been taking short-acting, inhaled $beta_2$-agonists on a regular basis (e.g., q.i.d.) should be instructed to discontinue the regular use of these drugs and use them only for symptomatic relief if they develop acute asthma symptoms while taking Serevent Inhalation Aerosol (see PRECAUTIONS: Information for Patients).

3. Watch for Increasing Use of Short-Acting, Inhaled $Beta_2$-Agonists, Which Is a Marker of Deteriorating Asthma: Asthma may deteriorate acutely over a period of hours or chronically over several days or longer. If the patient's short-acting, inhaled $beta_2$-agonist becomes less effective or the patient needs more inhalations than usual, this may be a marker of destabilization of asthma. In this setting, the patient requires immediate re-evaluation with reassessment of the treatment regimen, giving special consideration to the possible need for corticosteroids. If the patient uses four or more inhalations per day of a short-acting, inhaled $beta_2$-agonist for 2 or more consecutive days, or if more than one canister (200 inhalations per canister) of short-acting, inhaled $beta_2$-agonist is used in an 8-week period in conjunction with Serevent Inhalation Aerosol, then the patient should consult the physician for re-evaluation. **Increasing the daily dosage of Serevent Inhalation Aerosol in this situation is not appropriate. Serevent Inhalation Aerosol should not be used more frequently than twice daily (morning and evening) at the recommended dose of two inhalations.**

4. Do Not Use Serevent Inhalation Aerosol as a Substitute for Oral or Inhaled Corticosteroids: There are no data demonstrating that Serevent Inhalation Aerosol has a clinical anti-inflammatory effect and could be expected to take the place of, or reduce the dose of corticosteroids. Patients who already require oral or inhaled corticosteroids for treatment of asthma should be continued on this type of treatment even if they feel better as a result of initiating Serevent Inhalation Aerosol. Any change in corticosteroid dosage should be made ONLY after clinical evaluation (see PRECAUTIONS: Information for Patients).

5. Do Not Exceed Recommended Dosage: As with other inhaled $beta_2$-adrenergic drugs, Serevent Inhalation Aerosol should not be used more often or at higher doses than recommended. Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Large doses of inhaled or oral salmeterol (12 to 20 times the recommended dose) have been associated with clinically significant prolongation of the QT interval, which has the potential for producing ventricular arrhythmias.

6. Paradoxical Bronchospasm: As with other inhaled asthma medication, paradoxical bronchospasm (which can be life threatening) has been reported following the use of Serevent Inhalation Aerosol. If it occurs, treatment with Serevent Inhalation Aerosol should be discontinued immediately and alternative therapy instituted.

7. Immediate Hypersensitivity Reactions: Immediate hypersensitivity reactions may occur after administration of Serevent Inhalation Aerosol, as demonstrated by rare cases of urticaria, angioedema, rash, and bronchospasm.

8. Upper Airway Symptoms: Symptoms of laryngeal spasm, irritation, or swelling, such as stridor and choking, have been reported rarely in patients receiving Serevent Inhalation Aerosol.

PRECAUTIONS:

General: 1. Use With Spacer or Other Devices: The safety and effectiveness of Serevent® Inhalation Aerosol when used with a spacer or other devices have not been adequately studied.

2. Cardiovascular and Other Effects: No effect on the cardiovascular system is usually seen after the administration of inhaled salmeterol in recommended doses, but the cardiovascular and central nervous system effects seen with all sympathomimetic drugs (e.g., increased blood pressure, heart rate, excitement) can occur after use of Serevent Inhalation Aerosol and may require discontinuation of the drug. Salmeterol, like all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension; in patients with convulsive disorders or thyrotoxicosis; and in patients who are unusually responsive to sympathomimetic amines.

As has been described with other beta-adrenergic agonist bronchodilators, clinically significant changes in systolic and/or diastolic blood pressure, pulse rate, and electrocardiograms have been seen infrequently in individual patients in controlled clinical studies with salmeterol.

3. Metabolic Effects: Doses of the related $beta_2$-adrenoceptor agonist albuterol, when administered intravenously, have been reported to aggravate pre-existing diabetes mellitus and ketoacidosis. No effects on glucose have been seen with Serevent Inhalation Aerosol at recommended doses. Administration of $beta_2$-adrenoceptor agonists may cause a decrease in serum potassium, possibly through intracellular shunting, which has the potential to increase the likelihood of arrhythmias. The decrease is usually transient, not requiring supplementation.

Clinically significant changes in blood glucose and/or serum potassium were seen rarely during clinical studies with long-term administration of Serevent Inhalation Aerosol at recommended doses.

Information for Patients: See illustrated Patient's Instructions for Use leaflet. **SHAKE WELL BEFORE USING.**

It is important that patients understand how to use Serevent Inhalation Aerosol appropriately and how it should be used in relation to other asthma medications they are taking. Patients should be given the following information:

1. Shake well before using.

2. The recommended dosage (two inhalations twice daily, morning and evening) should not be exceeded.

3. Serevent Inhalation Aerosol is not meant to relieve acute asthma symptoms and extra doses should not be used for that purpose. Acute symptoms should be treated with a short-acting, inhaled $beta_2$-agonist such as albuterol (the physician should provide the patient with such medication and instruct the patient in how if should be used).

4. The physician should be notified immediately if any of the following situations occur, which may be a sign of seriously worsening asthma.

- Decreasing effectiveness of short-acting, inhaled $beta_2$-agonists
- Need for more inhalations than usual of short-acting, inhaled $beta_2$-agonists
- Use of four or more inhalations per day of a short-acting $beta_2$-agonist for 2 or more days consecutively
- Use of more than one canister of a short-acting, inhaled $beta_2$-agonist in an 8-week period (i.e., canister with 200 inhalations)

5. Serevent Inhalation Aerosol should not be used as a substitute for oral or inhaled corticosteroids. The dosage of these medications should not be changed and they should not be stopped without consulting the physician, even if the patient feels better after initiating treatment with Serevent Inhalation Aerosol.

6. Patients should be cautioned regarding potential adverse cardiovascular effects, such as palpitations or chest pain, related to the use of additional $beta_2$-agonist.

7. In patients receiving Serevent Inhalation Aerosol, other inhaled medications should be used only as directed by the physician.

8. When using Serevent Inhalation Aerosol to prevent exercise-induced bronchospasm, patients should take the dose at least 30 to 60 minutes before exercise.

Drug Interactions: ***Short-Acting Beta-Agonists:*** In the two 3-month, repetitive-dose clinical trials (n=184), the mean daily need for additional $beta_2$-agonist use was 1 to 1½ inhalations per day, but some patients used more. Eight percent of patients used at least eight inhalations per day at least on one occasion. Six percent used 9 to 12 inhalations at least once. There were 15 patients (8%) who averaged over four inhalations per day. Four of these used an average of 8 to 11 inhalations per day. In these 15 patients there was no observed increase in frequency of cardiovascular adverse

Serevent® (salmeterol xinafoate) Inhalation Aerosol

events. The safety of concomitant use of more than eight inhalations per day of short-acting beta$_2$-agonists with Serevent Inhalation Aerosol has not been established. In 15 patients who experienced worsening of asthma while receiving Serevent Inhalation Aerosol, nebulized albuterol (one dose in most) led to improvement in forced expiratory volume in 1 second (FEV_1) and no increase in occurrence of cardiovascular adverse events.

Monoamine Oxidase Inhibitors and Tricyclic Antidepressants: Salmeterol should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants because the action of salmeterol on the vascular system may be potentiated by these agents.

Corticosteroids and Cromoglycate: In clinical trials, inhaled corticosteroids and/or inhaled cromolyn sodium did not alter the safety profile of Serevent Inhalation Aerosol when administered concurrently.

Methylxanthines: The concurrent use of intravenously or orally administered methylxanthines (e.g., aminophylline, theophylline) by patients receiving Serevent Inhalation Aerosol has not been completely evaluated. In one clinical trial, 87 patients receiving Serevent Inhalation Aerosol 42 mcg twice daily concurrently with a theophylline product had adverse event rates similar to those in 71 patients receiving Serevent Inhalation Aerosol without theophylline. Resting heart rates were slightly higher in the patients on theophylline but were little affected by Serevent Inhalation Aerosol therapy.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In an 18-month oral carcinogenicity study in CD-mice, salmeterol xinafoate caused a dose-related increase in the incidence of smooth muscle hyperplasia, cystic glandular hyperplasia, and leiomyomas of the uterus and a dose-related increase in the incidence of cysts in the ovaries. A higher incidence of leiomyosarcomas was not statistically significant; tumor findings were observed at oral doses of 1.4 and 10 mg/kg, which gave 9 and 63 times, respectively, the human exposure based on rodent:human AUC comparisons.

Salmeterol caused a dose-related increase in the incidence of mesovarian leiomyomas and ovarian cysts in Sprague Dawley rats in a 24-month inhalation/oral carcinogenicity study. Tumors were observed in rats receiving doses of 0.68 and 2.58 mg/kg per day (about 55 and 215 times the recommended clinical dose [mg/m^2]). These findings in rodents are similar to those reported previously for other beta-adrenergic agonist drugs. The relevance of these findings to human use is unknown.

No significant effects occurred in mice at 0.2 mg/kg (1.3 times the recommended clinical dose based on comparisons of the AUCs) and in rats at 0.21 mg/kg (15 times the recommended clinical dose on a mg/m^2 basis).

Salmeterol xinafoate produced no detectable or reproducible increases in microbial and mammalian gene mutation *in vitro*. No blastogenic activity occurred *in vitro* in human lymphocytes or *in vivo* in a rat micronucleus test. No effects on fertility were identified in male and female rats treated orally with salmeterol xinafoate at doses up to 2 mg/kg orally (about 160 times the recommended clinical dose on a mg/m^2 basis).

Pregnancy: ***Teratogenic Effects: Pregnancy Category C:*** No significant effects of maternal exposure to oral salmeterol xinafoate occurred in the rat at doses up to the equivalent of about 160 times the recommended clinical dose on a mg/m^2 basis. Dutch rabbit fetuses exposed to salmeterol xinafoate *in utero* exhibited effects characteristically resulting from beta-adrenoceptor stimulation; these included precocious eyelid openings, cleft palate, sternebral fusion, limb and paw flexures, and delayed ossification of the frontal cranial bones. No significant effects occurred at 0.6 mg/kg given orally (12 times the recommended clinical dose based on comparison of the AUCs).

New Zealand White rabbits were less sensitive since only delayed ossification of the frontal bones was seen at 10 mg/kg given orally (approximately 1,600 times the recommended clinical dose on a mg/m^2 basis). Extensive use of other beta-agonists has provided no evidence that these class effects in animals are relevant to use in humans. There are no adequate and well-controlled studies with Serevent Inhalation Aerosol in pregnant women. Serevent Inhalation Aerosol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in Labor and Delivery: There are no well-controlled human studies that have investigated effects of salmeterol on preterm labor or labor at term. Because of the potential for beta-agonist interference with uterine contractility, use of Serevent Inhalation Aerosol during labor should be restricted to those patients in whom the benefits clearly outweigh the risks.

Nursing Mothers: Plasma levels of salmeterol after inhaled therapeutic doses are very low (85 to 200 pg/mL) in humans. In lactating rats dosed with radiolabeled salmeterol, levels of radioactivity were similar in plasma and milk. In rats, concentrations of salmeterol in plasma and milk were similar. The xinafoate moiety is also transferred to milk in rats at concentrations of about half the corresponding level in plasma. However, since there is no experience with use of Serevent Inhalation Aerosol by nursing mothers, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. Caution should be exercised when salmeterol xinafoate is administered to a nursing woman.

Pediatric Use: The safety and effectiveness of Serevent Inhalation Aerosol in children younger than 12 years of age have not been established.

Geriatric Use: Of the total number of patients who received Serevent Inhalation Aerosol in all clinical studies, 241 were 65 years and older. Geriatric patients (65 years and older) with reversible obstructive airway disease were evaluated in four well-controlled studies of 3 weeks' to 3 months' duration. Two placebo-controlled, crossover studies evaluated twice-daily dosing with salmeterol for 21 to 28 days in 45 patients. An additional 75 geriatric patients were treated with salmeterol for 3 months in two large parallel-group, multicenter studies. These 120 patients experienced increases in AM and PM peak expiratory flow rate and decreases in diurnal variation in peak expiratory flow rate similar to responses seen in the total populations of the two latter studies. The adverse event type and frequency in geriatric patients were not different from those of the total populations studied.

No apparent differences in the efficacy and safety of Serevent Inhalation Aerosol were observed when geriatric patients were compared with younger patients in clinical trials. As with other beta$_2$-agonists, however, special caution should be observed when using Serevent Inhalation Aerosol in elderly patients who have concomitant cardiovascular disease that could be adversely affected by this class of drug. Based on available data, no adjustment of salmeterol dosage in geriatric patients is warranted.

ADVERSE REACTIONS: Adverse reactions to salmeterol are similar in nature to reactions to other selective beta$_2$-adrenoceptor agonists, i.e., tachycardia; palpitations; immediate hypersensitivity reactions, including urticaria, angioedema, rash, bronchospasm (see WARNINGS); headache; tremor; nervousness, and paradoxical bronchospasm (see WARNINGS).

Two multicenter, 12-week, controlled studies have evaluated twice-daily doses of Serevent® Inhalation Aerosol in patients 12 years of age and older with asthma. The following table reports the incidence of adverse events in these two studies.

Serevent® (salmeterol xinafoate) Inhalation Aerosol

Adverse Experience Incidence in Two Large 12-Week Clinical Trials*

Adverse Event Type	Percent of Patients		
	Placebo n=187	Serevent 42 mcg b.i.d. n=184	Albuterol 180 mcg q.i.d. n=185
Ear, nose, and throat			
Upper respiratory tract infection	13	14	16*
Nasopharyngitis	12	14	11
Disease of nasal cavity/sinus	4	6	1
Sinus headache	2	4	<1
Gastrointestinal			
Stomachache	0	4	0
Neurological			
Headache	23	28	27
Tremor	2	4	3
Respiratory			
Cough	6	7	3
Lower respiratory infection	2	4	2

* The only adverse experience classified as serious was one case of upper respiratory tract infection in a patient treated with albuterol.

The table above includes all events (whether considered drug related or nondrug related by the investigator) that occurred at a rate of over 3% in the Serevent Inhalation Aerosol treatment group and were more common in the Serevent Inhalation Aerosol group than in the placebo group.

Pharyngitis, allergic rhinitis, dizziness/giddiness, and influenza occurred at 3% or more but were equally common on placebo. Other events occurring in the Serevent Inhalation Aerosol treatment group at a frequency of 1% to 3% were as follows:

Cardiovascular: Tachycardia, palpitations.
Ear, Nose, and Throat: Rhinitis, laryngitis.
Gastrointestinal: Nausea, viral gastroenteritis, nausea and vomiting, diarrhea, abdominal pain.
Hypersensitivity: Urticaria.
Mouth and Teeth: Dental pain.
Musculoskeletal: Pain in joint, back pain, muscle cramp/contraction, myalgia/myositis, muscular soreness.
Neurological: Nervousness, malaise/fatigue.
Respiratory: Tracheitis/bronchitis.
Skin: Rash/skin eruption.
Urogenital: Dysmenorrhea.
In small dose-response studies, tremor, nervousness, and palpitations appeared to be dose related.

Postmarketing Experience: In extensive US and worldwide postmarketing experience, serious exacerbations of asthma, including some that have been fatal, have been reported. In most cases, these have occurred in patients with severe asthma and/or in some patients in whom asthma has been acutely deteriorating (see WARNINGS no. 1), but they have occurred in a few patients with less severe asthma as well. It was not possible from these reports to determine whether Serevent Inhalation Aerosol contributed to these events or simply failed to relieve the deteriorating asthma.

Postmarketing experience includes rare reports of upper airway symptoms of laryngeal spasm, irritation, or swelling, such as stridor and choking.

OVERDOSAGE: Overdosage with salmeterol may be expected to result in exaggeration of the pharmacologic adverse effects associated with beta-adrenoceptor agonists, including tachycardia and/or arrhythmia, tremor, headache, and muscle cramps. Overdosage with salmeterol can lead to clinically significant prolongation of the QT_c interval, which can produce ventricular arrhythmias. Other signs of overdosage may include hypokalemia and hyperglycemia.

In these cases, therapy with Serevent® Inhalation Aerosol and all beta-adrenergic–stimulant drugs should be stopped, supportive therapy provided, and judicious use of a beta-adrenergic blocking agent should be considered, bearing in mind the possibility that such agents can produce bronchospasm. Cardiac monitoring is recommended in cases of overdosage.

As with all sympathomimetic pressurized aerosol medications, cardiac arrest and even death may be associated with abuse of Serevent Inhalation Aerosol.

Rats and dogs survived the maximum practicable inhalation doses of salmeterol of 2.9 and 0.7 mg/kg, respectively. The maximum nonlethal oral doses in mice and rats were approximately 150 mg/kg and >1,000 mg/kg, respectively.

Dialysis is not appropriate treatment for overdosage of Serevent Inhalation Aerosol.

Allen & Hanburys
Division of Glaxo Wellcome Inc.
Research Triangle Park, NC 27709

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posure. CONCLUSIONS: For residents to learn effective prevention counseling strategies, systematic, reinforced preventive educational curricula must become an institutionalized part of residency training.

Use of Dexamethasone in the Outpatient Management of Acute Laryngotracheitis—MN Cruz, G Stewart, N Rosenberg. Pediatrics 1995;96 (2):220.

OBJECTIVE: Recent studies have demonstrated that a single intramuscular injection of dexamethasone (0.6 mg/kg) shortens the duration and severity of illness in hospitalized patients with acute viral laryngotracheitis (croup). Our objective was to determine if dexamethasone has a role in the outpatient management of patients with acute viral croup of moderate severity. METHODS: Patients, 6 months to 5 years of age, who came to the emergency department (ED) with acute viral croup, a croup score of at least 2 (range 0 to 17), and a disposition of discharge were randomized in a double-blind fashion to receive a single intramuscular injection of dexamethasone, 0.6 mg/kg, or an equal volume of normal saline before discharge from the ED. Patients were excluded if they had any structural abnormalities, had received any steroids in the preceding 24 hours, or if they required β-agonist therapy, more than one racemic epinephrine treatment, or hospitalization. Patients were followed up by telephone 24 hours and 7 to 10 days after discharge to determine whether additional medical attention was sought for perceived lack of improvement or worsening of symptoms. Secondary outcome included the parents' perception of how the child was doing at 24 hours, based on a 4-point ordinal scale: worse (1), same (2), improved (3), symptoms resolved (4), and the number of days it took for complete recovery. RESULTS: Of the 38 patients comprising the study group, 19 received dexamethasone. The median age was 19 months (range 6 to 66 months), and median pretreatment croup score was 3 (range 2 to 5) for both groups. The number of patients requiring racemic epinephrine was similar in both groups. Five patients sought additional medical attention within 48 hours. Four of the five patients had received placebo (21% of the placebo group) and one had received dexamethasone (5% of the steroid group) (not statistically significant). At the 24-hour telephone follow-up, significantly more patients in the dexamethasone group had a score consistent with improvement compared with placebo (84% vs 42%, $p = 0.003$). There was no difference in the number of days for symptoms to completely resolve between the two groups. CONCLUSION: The use of dexamethasone in the outpatient management of viral croup was associated with a reduction in severity of illness within 24 hours after treatment. Patients with viral croup of moderate severity should be considered as candidates for the use of dexamethasone before discharge from the ED.

Effect of Chestwall Distortion on the Measurement of Pulmonary Mechanics in Preterm Infants—GS Neto, T Gerhardt, N Claure, S Duara, E Bancalari. Pediatr Pulmonol 1995; 20:34.

The purpose of this study was to determine the effect of chestwall distortion (CWD) on the measurement of pulmonary compliance (C_L) and resistance (R_L). Inductance plethysmography was used in 15 preterm infants to determine CWD as total compartmental displacement ratio (TCDR) and out of phase movement between ribcage and abdomen as phase shift (PS). Flow was measured by pneumotachography and esophageal pressure change (Pe) with a water-filled catheter. C_L and R_L were calculated by linear regression analysis. Seven infants (mean ± SD: BW, 1,484 ± 186 g, GA 32.4 ± 2.2 weeks, age 8.7 ± 4.7 days) had a breathing pattern characterized by episodes with a high degree of CWD, followed by periods with minimal CWD (distortion group). In this group lung function measurements were analyzed separately during periods with and without CWD. The remaining 8 infants (BW, 1,244 ± 233 g, GA 30.4 ± 2.4 weeks, age 7.4 ± 3.1 days) always breathed with minimal CWD, and the measurements in this group (non-distortion group) were used as a reference for the values obtained in the distortion group. Measurements of TCDR, PS, C_L, R_L, and tidal volume (V_T) obtained in the absence of CWD were not significantly different between distortion and non-distortion groups. The measurements obtained in the presence of CWD showed a significantly higher TCDR and PS, but C_L and R_L were not significantly different from the C_L and R_L measurements obtained in the distortion and non-distortion groups in the absence of CWD. The only significant effect of CWD was a reduction in V_T. The results indicate that the moderate degree of CWD observed in the study population does not significantly contribute to the variability in C_L and R_L measurements in preterm infants.

Independent Parental Administration of Prednisone in Acute Asthma: A Double-Blind, Placebo-Controlled, Crossover Study—CC Grant, AK Duggan, C DeAngelis. Pediatrics 1995;96 (2):224.

OBJECTIVE: To determine the effectiveness of a single dose of prednisone administered by a parent to a child early in an asthma attack. DESIGN: A randomized, double-blind, placebo-controlled, crossover study with children enrolled for 12 months (6 months prednisone, 6 months placebo). SETTING: A primary-care clinic and emergency department of an inner-city teaching hospital from March 1992 through May 1993. CHILDREN: Children 2 to 14 years of age enrolled in this clinic who had made two or more outpatient (emergency department or primary-care clinic) visits for acute asthma in the preceding year. SELECTION: There were 204 eligible children, of whom 86 were contacted and enrolled; of these, 78 (91%) completed the study. INTERVENTION: Capsules containing prednisone (2 mg/kg up to 60 mg) or placebo. Parents were instructed to give their child one capsule for an asthma attack that had not improved after a dose of the child's regular acute asthma medicine. MEASUREMENTS: Parents were interviewed every 3 months. Computerized patient records and chart reviews were used to verify parent reports. Outcome measures were the numbers of outpatient visits and hospitalizations for treatment of acute asthma. RESULTS: Neither the total number of attacks nor the number for which medicine was used differed significantly by arm of study. There was a larger number of attacks resulting in outpatient visits when children were in the group that received prednisone (1.1 ± 0.59 versus 0.59 ± 0.86). This trend was less pronounced but persisted when limited to attacks for which the medicine was given (0.58 ± 0.99 versus 0.35 ± 0.55). Neither the number of attacks resulting in admission nor the number of hospital days differed significantly by arm of study. CONCLUSIONS: A single dose of prednisone available for use at home early in an asthma attack was associated with an increase in outpatient visits made for acute asthma. When prednisone was given for an attack, there was no reduction in outpatient visits. This intervention can not be recommended for children with asthma. These results should be confirmed in other pediatric populations. *See the related commentary: **Steroids and Asthma**—GG Shapiro. Pediatrics 1995;96(2):347-348.*

Steroid Controversy in Sepsis and Septic Shock: A Meta-Analysis—R Lefering, EAM Neugebauer. Crit Care Med 1995;23(7):1294.

OBJECTIVE: The use of corticosteroids in patients with sepsis or septic shock has been controversial for many decades. Clinical studies have reported beneficial, as well as negative results. We conducted a meta-analysis to assess the clinical evidence and to evaluate treatment effects in specific subgroups of patients. DESIGN: Meta-analysis. DATA SOURCES: A comprehensive search of the literature revealed 49 publications investigating the effect of corticosteroids in patients with sepsis and septic shock. STUDY SELECTION: Only 10 of the 49 publications were prospective, randomized, controlled trials with an exact description of dosage and regimen. DATA EXTRACTION: Treatment effects on mortality were calculated as rate differences in each study (negative values favor steroids), and were combined with respect to the variability in each study. DATA SYNTHESIS: Only one study showed a significantly positive effect of steroid treatment. Overall, no positive effect was observed: –0.2% (95% confidence interval: –9.2, 8.8). There were no differences observed when comparing low- versus high-dose or type of corticosteroid used. Comparing patients with proven Gram-positive or Gram-

negative infection showed a slight but not significant difference. The Gram-negative group demonstrated better outcome (−5.6%, vs 1.8%). A quality rating of each trial showed a remarkable increase in quality over time. Adverse events (gastrointestinal bleeding, secondary infections, hyperglycemia) were not more frequent in patients treated with steroids compared with controls. CONCLUSIONS: No overall beneficial effect of corticosteroids in patients with septic shock was observed; however, there is some evidence for a positive effect in patients with Gram-negative septicemia. *See the related editorial:* ***Sepsis and Controlled Clinical Trials: The Odyssey*****—***RC Bone. Crit Care Med 1995;23(7):1165-1166.*

Use of Health Services by African-American Children with Asthma on Medicaid—P Lozano, FA Connell, TD Koepsell. JAMA 1995;274 (6):469.

OBJECTIVE: To determine whether African-American children with asthma use more emergency department (ED) and inpatient medical services and fewer preventive services than white children with similar insurance coverage and family income. DESIGN: Historical cohort study using Medicaid claims data. SETTING: Aid to Families with Dependent Children enrollees aged 3 through 17 years in the Seattle-Tacoma, Washington, metropolitan area. PATIENTS: All 576 African-American children and 1,369 white children receiving services for asthma between June 1988 and December 1992. MAIN OUTCOME MEASURES: Utilization of asthma services (ED, inpatient, office visits, and pharmacy) and well-child services and associated Medicaid reimbursements. RESULTS: African-American children were more likely than white children to make ED visits or to be hospitalized for asthma; adjusted odds ratios (ORs) were 1.70 (95% confidence interval [CI], 1.34 to 2.15) and 1.42 (95% CI, 1.03 to 1.96), respectively. African-American children were less likely to have made an office visit for asthma; the adjusted OR was 0.48 (95% CI, 0.26 to 0.85). The two groups were similarly likely to have filled a prescription for an asthma medication and to have made a well-child visit. Per capita payments for asthma services were 24% higher for African-American children: $436 versus $350 per child-year. CONCLUSIONS: Higher use of ED and inpatient services for asthma among African-American children using Medicaid (compared with white children) cannot be fully explained by poverty or inadequate health insurance. Furthermore, these children appear to make disproportionately few office visits for asthma, suggesting suboptimal use of preventive services for asthma. In contrast, the comparable use of well-child visits in the two groups suggests the problem may not be in access to care in general, but there may be specific problems in the successful management of chronic diseases such as asthma among African-American children.

Significant Reduction in Methicillin-Resistant *Staphylococcus aureus* Ventilator-Associated Pneumonia Associated with the Institution of a Prevention Protocol—MJ Rumbak, MR Cancio. Crit Care Med 1995;23(7):1200.

OBJECTIVE: To determine whether the institution of a methicillin-resistant *Staphylococcus aureus* prevention protocol was associated with a decrease in methicillin-resistant *S. aureus* ventilator-associated pneumonia in long-term, acute care ventilator patients. DESIGN: A retrospective chart review comparing the number of episodes of clinical pneumonia per patient ventilator day in the 12 months preceding and 24 months following the introduction of the protocol. SETTING: University affiliated, long-term, acute care ventilator hospital. PATIENTS: Long-term, acute care ventilated patients who presented with clinical pneumonia. INTERVENTIONS: Addition of a methicillin-resistant *S. aureus* prevention protocol. In addition to universal precautions, the protocol consisted of mupirocin 2% ointment applied to the anterior nares, and whole body washing with chlorhexidine. All patients were given mupirocin and chlorhexidine twice weekly. Patients were cohorted in the same room if they were, or had been, infected or colonized with methicillin-resistant *S. aureus* in any anatomical location or at any time. This procedure replaced strict isolation of methicillin-resistant *S. aureus*-infected or colonized individuals. MEASUREMENTS AND MAIN RESULTS: Clinical pneumonia was diagnosed when a patient developed fever, bronchorrhea, increased white blood cell count, methicillin-resistant *S. aureus* isolated from the tracheal aspirate, and new or increasing infiltrate on chest roentgenograph. During the 12 months preceding the protocol, there were 0.2% episodes of methicillin-resistant *S. aureus* ventilator-associated pneumonia per ventilated patient day compared with 0.026% in the 24 months after the protocol ($p < 0.001$). The relative and absolute risk reductions associated with the introduction of the protocol were 87% and 6, respectively. CONCLUSIONS: The period following the institution of the protocol showed a significant reduction in episodes of clinical pneumonia compared with the 12-month period preceding the use of the protocol ($p < 0.001$). Thus, we conclude that the introduction of this protocol is associated with a significant decrease in methicillin-resistant *S. aureus* ventilator-associated pneumonia.

Is Hand Washing Really Needed in an Intensive Care Unit?—LJ Rossoff, M Borenstein, HD Isenberg. Crit Care Med 1995;23(7):1211.

OBJECTIVES: To determine whether a rigorous antiseptic hand washing of bare hands with 4% chlorhexidine and alcohol reduced fingertip microbial colonization as compared with the use of boxed, clean, nonsterile latex gloves. In addition, to investigate if aseptic donning technique and/or a prior hand washing would reduce the level of glove contamination. DESIGN: Prospective, randomized, crossover design, with each subject serving as his/her own control. SETTING: University intensive care unit. SUBJECTS: Forty-three intensive care nurses. INTERVENTIONS: The fingertips of 20 nurses were cultured before and after a strict antiseptic hand washing and before and after the routine and aseptic donning of sterile gloves. Subsequently, the fingertips of 43 nurses were cultured before and after the casual donning of nonsterile gloves over unwashed hands and before and after a strict antiseptic hand washing. Fingertip cultures were plated directly on agar, incubated for 24 hours, and counted and recorded as the number of colony-forming units (cfu) for each hand. Different colony types were then subcultured. MEASUREMENTS AND MAIN RESULTS: Hand washing with antiseptic reduced colonization from 84 to 2 cfu ($p < 0.001$). The proportion of cases with ≥ 200 cfu/hand was reduced from 30% to 9%. Aseptic or casual donning of sterile gloves, with or without prior antiseptic hand washing, resulted in consistently low glove counts between 0 and 1.25 cfu. Nonsterile gloves casually donned over washed or unwashed bare hands diminished the bioburden to 2.17 and 1.34 cfu, respectively. No qualitative difference was found in the microorganisms recovered from gloved or bare hands. CONCLUSIONS: Antiseptic hand washing and the use of nonsterile gloves over unwashed hands confer similar reductions in the number of microorganisms. There is no additional benefit with the use of aseptic donning technique, prior antiseptic hand washing, or the use of individually packaged sterile gloves.

Survival and Functional Outcome of Children Requiring Mechanical Ventilation during Therapy for Acute Bacterial Meningitis—ET Madagame, PL Havens, JM Bresnahan, KL Babel, ML Splaingard. Crit Care Med 1995; 23(7):1279.

OBJECTIVE: To determine predictors of survival and functional outcome of pediatric patients requiring mechanical ventilation during therapy for acute bacterial meningitis. DESIGN: Retrospective case series. SETTING: Pediatric intensive care unit (ICU) at a midwestern tertiary care children's hospital. PATIENTS: Consecutive sample of 32 patients (median age 9.8 months; range 9 days to 12 years) from 1985 to 1990 with acute bacterial meningitis severe enough to require mechanical ventilation during therapy. Of these patients, 59% were female and 59% were white. INTERVENTIONS: None. MEASUREMENTS AND MAIN RESULTS: Data were analyzed to identify predictors of survival and functional status after hospital discharge. Variables included were vital signs, Pediatric Risk of Mortality (PRISM) score within the first 24 hours of hospitalization, Glasgow Coma Score, and course of illness. Functional

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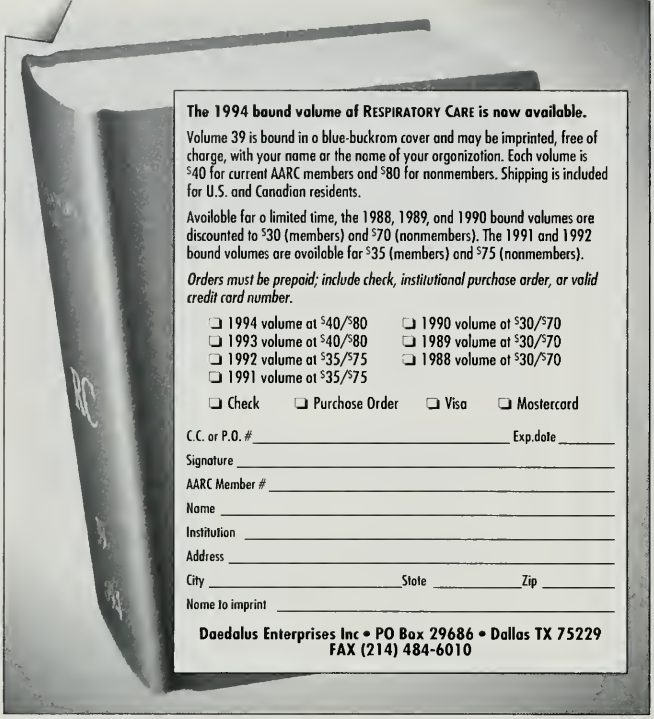

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status was assessed at hospital discharge and at follow-up (median follow-up: 41.5 months, range 7 to 77) in the areas of locomotion, self-care, and communication. There were 10 inhospital deaths. The 22 survivors formed three groups. At hospital discharge, seven children showed no functional disability. Seven patients were dependent in all three areas of function at discharge, with six still dependent at follow-up evaluation. Eight patients showed mild to moderate impairment in at least one area of function at hospital discharge. At follow-up, four of these eight patients demonstrated no functional disability, one had improved status, two were unchanged, and one was lost to follow-up. The best predictor of death and functional status at follow-up was the admission PRISM score. Hypotension and tachyeardia within the first 24 hours after pediatric ICU admission were strongly associated with poor outcome. CONCLUSIONS: After bacterial meningitis in children whose care included mechanical ventilation, half of the patients died or survived with severe functional deficits. Patients with mild or moderate functional deficits at hospital discharge improved with time.

Resistance to Penicillin and Cephalosporin and Mortality from Severe Pneumococcal Pneumonia in Barcelona, Spain—R Pallares, J Liñares, M Vadillo, C Cabellos, F Manresa, PF Viladrich, R Martin, F Gudiol. N Engl J Med 1995;333(8):474.

BACKGROUND: Penicillin-resistant strains of *Streptococcus pneumoniae* are now found worldwide, and strains with resistance to cephalosporin are being reported. The appropriate antibiotic therapy for pneumococcal pneumonia due to resistant strains remains controversial. METHODS: To examine the effect of resistance to penicillin and cephalosporin on mortality, we conducted a 10-year, prospective study in Barcelona of 504 adults with culture-proved pneumococcal pneumonia. RESULTS: Among the 504 patients, 145 (29%) had penicillin-resistant strains of *S. pneumoniae* (minimal inhibitory concentration [MIC] of penicillin G, 0.12 to 4.0 μg per milliliter), and 31 patients (6%) had cephalosporin-resistant strains (MIC of cefriaxone or cefotaxime, 1.0 to 4.0 μg per milliliter). Mortality was 38% in patients with penicillin-resistant strains, as compared with 24% in patients with penicillin-sensitive strains ($p = 0.001$). However, after the exclusion of patients with polymicrobial pneumonia and adjustment for other predictors of mortality, the odds ratio for mortality in patients with penicillin-resistant strains was 1.0 (95% confidence interval, 0.5 to 1.9; $p = 0.84$). Among patients treated with penicillin G or ampicillin, the mortality was 25% in the 24 with penicillin-resistant strains and 19% in the 126 with penicillin-sensitive strains ($p = 0.51$). Among patients treated with ceftriaxone or cefotaxime, the mortality was 22% in the 59 with penicillin-resistant strains and 25% in the 127 with penicillin-sensitive strains ($p = 0.64$). The frequency of resistance to cephalosporin increased from 2% in 1984-1988 to 9% in 1989-1993 ($p = 0.002$). Mortality was 26% in patients with cephalosporin-resistant *S. pneumoniae* and 28% in patients with susceptible organisms ($p = 0.89$). Among patients treated with ceftriaxone or cefotaxime, mortality was 22% in the 18 with cephalosporin-resistant strains and 24% in the 168 with cephalosporin-sensitive organisms ($p = 0.64$). CONCLUSIONS: Current levels of resistance to penicillin and cephalosporin by *S. pneumoniae* are not associated with increased mortality in patients with pneumococcal pneumonia. Hence, these antibiotics remain the therapy of choice for this disease. *See the related editorial:* ***The Pneumococcus at the Gates****—A Tomasz. N Engl J Med 1995;333(8):514-515.*

Oxygen Status of Arterial and Mixed Venous Blood—O Siggaard-Andersen, N Fogh-Andersen, IH Gøthgen, VH Larsen. Crit Care Med 1995; 23(7):1284.

OBJECTIVES: To describe system requirements for determination of the oxygen status of the blood using the oxygen status algorithm, a computer program. To define the oxygen extra-activity, a term we propose, of the arterial blood and the oxygen extraction tension. To describe the different causes of tissue hypoxia, and the clinical interpretation of mixed venous oxygen tension and oxygen consumption rate. DATA SOURCES: Previous physiological and clinical studies related to oxygen status of the blood. DATA SYNTHESIS: The oxygen status algorithm calculates the oxygen extraction tension and generates the oxygen graph as an aid in interpreting oxygen status of the patient. A cybernetic scheme explains the causes of tissue hypoxia and forms the basis for the interpretation of changes in the mixed venous oxygen tension. A diagram with the mixed venous oxygen tension on the abscissa and the oxygen consumption rate on the ordinate illustrates the oxygen-flux-dependent oxygen-consumption rate. A graph shows the relationship between mixed venous oxygen tension and oxygen delivery. CONCLUSIONS: The oxygen status of arterial blood comprises three groups of quantities related to arterial oxygen tension, hemoglobin oxygen capacity, and hemoglobin oxygen affinity. Disturbances in one of these groups may be compensated by opposite changes in one or both of the other. The oxygen extraction tension indicates the degree of compensation, and mixed venous oxygen tension is the key parameter in evaluating the presence of a state of oxygen flux-dependent oxidative metabolism.

The Prevalence of Drug-Resistant *Streptococcus pneumoniae* in Atlanta—J Hofmann, MS Cetron, MM Farley, WS Baughman, RR Facklam, JA Elliott, KA Deaver, RF Breiman. N Engl J Med 1995;333(8):481.

BACKGROUND: *Streptococcus pneumoniae* is a major cause of illness, and the emergence of drug-resistant strains threatens to complicate the management of pneumococcal infections. We conducted a laboratory-based surveillance for drug-resistant *S. pneumoniae* among patients with invasive pneumococcal infections in Atlanta. METHODS: From January through October 1994, pneumococcal isolates from 431 patients with invasive disease in metropolitan Atlanta were serotyped and tested to determine their susceptibility to various antimicrobial agents. Susceptibility to the antimicrobial agents was defined according to guidelines established by the National Committee for Clinical Laboratory Standards. RESULTS: The annual incidence of invasive pneumococcal infection was 30 cases per 100,000 population. Isolates from 25% of the patients were resistant to penicillin (7% were highly resistant), and isolates from 26% were resistant to trimethoprim-sulfamethoxazole (7% highly resistant). Fifteen percent of the isolates were resistant to erythromycin, 9% to cefotaxime (4% were highly resistant), and 25% to multiple drugs. Drug-resistant pneumococci were found in both children and adults. Children under six years of age were more likely than older children and adults to have isolates resistant to multiple drugs or cefotaxime. Whites were more likely than blacks to have invasive pneumococcal infections caused by drug-resistant organisms. Among white children younger than six years, 41% of the *S. pneumoniae* isolates were resistant to penicillin. CONCLUSIONS: Drug-resistant strains of *S. pneumoniae* are common among both children and adults in Atlanta. Although blacks had a higher incidence of invasive pneumococcal infections than whites, whites were more likely to be infected with a drug-resistant isolate. Control of drug-resistant pneumococci will require more judicious use of antimicrobial agents and wider use of the pneumococcal polysaccharide vaccine.

A Behavioral Science Approach to Clinical Research

Basic Paradigms

Research can be defined simply as a systematic method of inquiry—a method of obtaining information pertaining to some question or set of questions. The nature of questions range from simple explanatory ones (What is lung cancer?), to those that pose predictive hypotheses about variables (Does age increase convalescence time for postoperative patients with chronic lung disease?), and is the basis for the choice of research design. As might be expected, two basic paradigms are available—experimental and nonexperimental.[1] The choice of paradigms is based on the nature of the question, the setting in which the research is to be conducted, and the background and disciplinary orientation of the researcher. These approaches are different in important ways, but both involve the basic components of the research process:

- research question or problem must be specifically identified;
- study must be designed in a technically sound manner;
- data must be collected and analyzed appropriately; and
- results must be accurately interpreted and communicated.

The experimental paradigm is one in which subjects are randomly allocated to a placebo-control or no-treatment group, against which a 'treatment' group can be compared on one or more important variables. Many of the original research articles published in RESPIRATORY CARE are of this type. The basic aim of this research approach is to control all extraneous influences so that the behavior of the dependent variable reflects the intervention, and nothing else. However, because of the control involved, experimental research is conducted in a somewhat artificial environment (possibly affecting external validity).[2,3]

In contrast, nonexperimental approaches to conducting research can be thought of as the complement of experimentation, and most studies in the behavioral sciences follow this paradigm. Nonexperimental researchers tend to observe, analyze, and describe subjects and events. When we examine these two research approaches, we find that each has certain strong points that must be weighed against its weaknesses to determine how the research question is to be studied. It is important to remember that the overall research process remains unchanged; only the methodology changes.

Behavioral Research Approach—Methodological Rigor

Sample Size

Many references are available to help behavioral researchers determine the minimum sample size that must be studied to adequately answer the research question. The issue is statistical power: the probability of rejecting a false null hypothesis.[4,5] In general, small and narrowly drawn samples limit the degree to which an investigator can generalize conclusions to a larger population. Therefore, it is important to consider the limitations of a small-sample study. When accepting a null hypothesis based on a small sample, particularly when the p value seems to approach significance, it is possible that an effect may reach significance with a larger sample. However, it is also possible that the 'trend' may disappear altogether. Results such as these suggest the need for further study. In our article,[6] the SIZE and CREDITS variables demonstrated p values close enough to α that we were unwilling to dismiss them automatically. Rather, we recommended that other investigators study these variables to see whether our results could be corroborated. We conclude that studies on small samples may be limited in terms of statistical power, but even so may be worth conducting.

Taming the Data

The data analysis usually follows data collection without alteration. However, in behavioral studies, the analysis plan may not be entirely clear until after the data are screened.[7] It seems logical in an observational study with few controls, some variables may turn out to be quite 'wild.'

Name That Distribution

Examining data distributions helps the researcher discern intemperance. During the screening phase, a researcher must look specifically for evidence of non-normality. A distribution is said to be normal when its values vary symmetrically about its most frequently occurring value. Tabachnick and Fidell[7] suggest that skewness and kurtosis are measurements that help us with this assessment. If these measures are in-

flated (certainly when they exceed an absolute value of 1.0), and the mean/standard deviation is ≤ 3, non-normality must be suspected. Statistical procedures are available for determining whether skewness and kurtosis are critically inflated; however, visual examination of the frequency distribution and descriptive statistics often suffice.[7]

Outlier, Outlier, Pants on Fire

Some computer-based statistical analysis software programs such as SAS[8] and SPSS[9] can identify outlying or extreme data points[7,10] in the frequency distributions and remove them from the analysis. This process may eliminate non-normality in a distribution. Otherwise, data transformation may be required in order to generate a normal distribution.[7] If several outliers exist, data may be figuratively suggesting that this is a group that may systematically vary from the rest of the sample and may warrant groupwise analysis. However, if the sample is small, an outlier analysis may not be feasible and outliers are usually lost.

Data, Data, Who's Got the Data

Some variables may be missing data. Two options should be considered—eliminate missing data cases or replace the missing values with a plausible substitute.[7,10] If several cases lack data they may comprise a group worth studying[7] as we did with the groups that did and did not have ACT scores.[6] If only a few cases are missing data, one can substitute the mean of the other values.[7,10] Also, if correlating variables are available, the missing value could be predicted by a regression equation.[7] If starting with a small sample and just a few cases of missing data, losing cases may critically impair the analysis. We recommend one of the substitution methods to preserve sample size.

Data Transformations

Several transforming options are available.[7] Data that have a mildly positive skew can be 'normalized' with square root transformation (taking the square root of each data point). Data with moderately positive skew require logarithm transformation, and those that are severely positively skewed require inverse transformation. Negatively skewed data require reflection (subtracting each data point from a constant value that exceeds the maximum data point) then square-root, logarithmic, or inverse transformation.[7] The choice of transformation for positively skewed data should be guided by the severity of the skew. When in doubt about whether to transform, Tabachnick and Fidell[7] suggest trying various transformations and examining the new distributions to see whether normality is achieved.

Downgrading

Some data cannot be normalized. However, analysis can continue by downgrading variables. Continuous variables are those that can take on any value ($-\infty$, $+\infty$), but can exist on the interval or ratio level.[12] Forcing data into nominal- (names only, no quantitative value) or ordinal- (ordered categories) level data constitutes downgrading. If the dependent variables are continuous and normally distributed, dependent variable means can be compared using parametric tests of significance (eg, *t* tests). If they are categorical or skewed, a nonparametric analysis will be required (eg, χ^2). Data screening also requires the investigator to examine bivariate scatterplots and plots of residuals for each dependent and potential independent variable.[7] Analyses comparing means and regression analyses require that linear relationships exist between variables. Nonlinearity can be easily seen from a bivariate plot.[4,5,7] Nonlinear variables must be downgraded or a nonparametric analysis must be applied.

Collinearity

Including two or more interrelated independent variables in multivariate analyses weakens the power to reject false null hypotheses and reflects incomplete data screening.[7] When two potential independent variables strongly correlate ($r \geq 0.70$) they are considered collinear in the sense that they are redundant measures.[7] Withholding the collinear variable least likely to contribute to explaining the variation in the dependent variable is the accepted procedure.[7] Examining a correlation matrix involving all continuous variables is the most efficient way to assess collinearity. An example of such a matrix is found in Table 1 of our paper.[6]

Examining correlations and descriptive statistics during data screening before hypotheses are posed may seem antithetic to good science. These procedures may appear to bias the result or they may confuse a reviewer who expects to see these values in the Results section. Constructing meaningful, simple, and easily understood hypotheses is an easier task after data have been screened. Otherwise, hypotheses become convoluted as the researcher tries to contend with each distributional contingency. Screening the data is fundamental to establishing a rigorous behavioral study. So long as accepted decision rules are described and followed, a researcher can avoid others' suspicions that the data have been inappropriately manipulated.

The Multivariate Jungle

Multivariate statistical analyses are often used by behavioral researchers because to explain why people behave in certain ways requires examining multiple outcome variables and more than one predictor variable. An appealing aspect of multivariate analyses is that the probability of committing a Type-I error (inferring an effect that does not truly exist) does not inflate as it would if each dependent and independent variable were analyzed separately.[12] However, before throwing all dependent and independent variables together to see what comes

out, be warned that multivariate analyses require large samples to retain statistical power—a tough criterion for most behavioral scientists for whom only small samples are possible. In such cases, the researcher should run as few defensible analyses as possible, adjusting α accordingly. Our study on student selection[6] is an example of how this was done in a multivariate analysis of variance (MANOVA) context.

MANOVA is also especially appropriate when the underlying factor under study is measured in more than one way. In our study,[6] we measured the *underlying entry-level* variable using GPA (grade-point average) and CSAE (CRTT self-assessment examination). Because of the way MANOVA proceeds, we assert that the *true entry-level* that we analyzed was larger than either measure could express alone. During MANOVA, the available dependent variable measures are linearly combined to form a new composite dependent variable.[7] ANOVA is then performed on the new variable. Therefore, the entry-level variable we studied was a broader, and potentially more important, measure than either GPA or CSAE had indicated, independently. This approach has particular intuitive appeal because after 3 semesters of a respiratory care curriculum, the students' skills are broader than GPA or test scores can measure. By analyzing both, we obtained a more complete picture of the important outcome predictors because the outcome was better defined.

Should an F test by MANOVA prove significant it is appropriate to follow with ANOVAs exploring the individual relationships among the variables. These post-hoc means comparisons do not inflate Type-I error because they are run as confirmatory tests of the initial analysis. However, selecting a post-hoc test to compare individual means is another issue and use of a liberal procedure is recommended for behavioral data. We used Fisher's Least Significant Difference test,[6] but others are available; and, for us, the choice warranted consultation with a trusted statistician who helped us develop a sensible analysis. Concern about diminishing the rigor of the means comparisons should not overcome the researcher when reminded that the test is run only after the initial indication that the means do differ. What we seek are results that make sense.

Multiple regression is an attractive method for an investigator who is faced with several potential predictors because these procedures account for shared variance among predictors.[7] Frequently, when analyzing several predictors simultaneously, a subset of important variables emerges with the remaining variables contributing nothing to the explanation of dependent variable variation or offering redundant explanations. Keep in mind that researchers are not limited to running only one regression when choosing among the array of procedures. The regression model can move forward (adding variables of decreasing explanatory strength) and backward (removing variables of increasing explanatory strength) to construct the model that accounts for the largest fraction of variation.[7] Given the array of choices, a researcher could become discouraged trying to find the one best regression analysis. In some situations, using more than one technique may be desirable. Demonstrating collaborative findings from more than one form of regression analysis can be one way to strengthen a conclusion. In our study,[6] we used 3 forms of regression analysis—Max R^2, forward selection, and backward selection.

Reporting the Results

One researcher's findings usually cannot express generalizable systematic relationships among behavioral variables. Duplication and extension of previous work help deepen understanding of human behavior. Meta-analyses are useful where several studies can be systematically combined to arrive at a larger more confidently stated and generalizable explanation of an effect.[10] Although an investigator's first interest may be to compare dependent variable means, standard deviations associated with those means should be included in the report. These data are required for meta-analysis[10] and exposing them publicly, encourages rigor. The researcher must compare the variances associated with group means to discern whether the homogeneity of variance assumption was met—particularly important for unequal-sized groups. Specific examples of work with groups having unequal variance and size are found in our paper.[6] When the standard deviation is not reported, reviewers may assume that the homogeneity of variances assumption was ignored.

In Conclusion

There is no single approach to studies in the behavioral sciences that, of itself, can ensure rigorous conduct and valid results. However, we assert that rigorously conducted behavioral studies involving post-collection data screening successfully employ multivariate analyses, acknowledge the limitations of the inferences, and report the results without reservation to permit, and even encourage, scrutiny. In general, we should not embrace the conclusions of any study until other studies support them. We hope our article on student selection[6] will inspire further research in this area.

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Authors' Note: As I prepared this editorial, I became impressed by the extent to which I had internalized portions of Barbara Tabachnick and Linda Fidell's *Using Multivariate Statistics*. I would be embarrassed by my reliance on this text as a guide to successfully conducting behavioral research except that its information is especially well presented. In my experience, their chapter on screening data prior to analysis has no rival. A former statistics professor of mine would have remarked with amazement that Tabachnick and Fidell were practitioners, not statisticians (and by implication, How could they write such a useful text? I am glad they did! RCS).

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Severity Scores in Respiratory Intensive Care: APACHE II Predicted Mortality Better Than SAPS II

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BACKGROUND: In recent years several scoring systems have been developed to describe the severity of illness, to establish the individual prognosis, and to group adult ICU patients by predicted risk of mortality. In addition, these scores can be used to measure and/or compare the quality of care in different ICUs. We compared the mortality predictions of the Acute Physiology and Chronic Health Evaluation (APACHE II) score and a new Simplified Acute Physiology Score (SAPS II) in patients with respiratory disease who require intensive care. PATIENTS & METHODS: We prospectively studied all 306 admissions from January 1, 1992 through December 31, 1994. McNemar and Hosmer-Lemeshow tests, and receiver operating characteristic (ROC) curves were used to describe and analyze our data. RESULTS: The average APACHE II score was 17.5 (SD 6.0), corresponding to a mean predicted death rate of 24.9% (SD 17.2%) as compared to an observed overall RICU mortality rate of 21.6%. The average SAPS II score was 39.1 (SD 11.1) corresponding to a mean predicted death rate of 26.0% (SD 18.4%). The ratio between the actual and predicted hospital mortality was 86% for APACHE II and 83% for SAPS II. Survivors had a significantly lower predicted risk of death than nonsurvivors ($p < 0.0001$) with both indices, and a higher Glasgow coma scale score ($p < 0.0001$). The ROC-curve analysis suggested the superior predictive ability of APACHE II in our patients. Area under the APACHE II ROC curve was 80.88% (standard error [SE] 2.89%), significantly larger ($p < 0.01$) than that found for SAPS II (73.52%, SE 3.61%). CONCLUSIONS: The APACHE II score was a good predictor of hospital outcome and better than SAPS II in our population. [Respir Care 1995;40(10):1042-1047]

Introduction

Several severity scores have been developed to classify intensive care unit (ICU) patients, to assess the quality of care of various ICUs, and to describe the case-mix of generalized or specialized ICUs.[1-5] These scores help to standardize the estimation of treatment effectiveness, the risk of hospital death, and the performance of various ICUs.[6]

The Acute Physiology and Chronic Health Evaluation scoring system (APACHE) was first introduced by Knaus and colleagues in 1981[7] and subsequently modified (APACHE II)[3] in 1985 to prognostically stratify acutely ill patients by predicted risk of death. Since then, this score has been used ex-

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None of the authors has a financial interest in any commercial products mentioned in this paper.

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tensively for a wide variety of pathologic conditions both in general and specific intensive care units.[8-21]

Recently, Le Gall and co-workers developed and validated a new simplified acute physiology score, SAPS II, which, like APACHE II, uses logistic regression modeling techniques, but a different combination of variables, to estimate the probability of hospital mortality for ICU patients.[22] We found no study comparing the two systems in patients with respiratory disease.

The aim of this study was to compare the performance of the APACHE II and SAPS II scoring systems in assessing outcome and the severity of illness in a series of patients admitted to a respiratory intensive care unit (RICU).

Patients & Methods

We prospectively examined all admissions to the RICU at S. Orsola Community Teaching Hospital (Bologna, Italy) from January 1, 1992 through December 31, 1994. Approval from the local ethics committee was not required for the anonymous use of data already collected for clinical purposes. Best Glascow coma scale (GCS) score, as recommended by other authors,[19] and the worst physiologic values relevant to the APACHE II and SAPS II score were recorded during the first 24 hours in the RICU and stored for later analysis in a Macintosh IIcx computer (Macintosh Corp, Cupertino CA), using a program written in a relational database (Mac + Fox Base 2.0a, Microsoft Corp, Redmond WA) by one of us (AM).

Scoring Systems

The APACHE II scoring system uses 11 weighted physiologic measurements (body temperature, mean arterial blood pressure, heart rate, respiratory rate, oxygenation (alveolar-arterial oxygen pressure difference [if $F_{DO_2} > 0.5$] or P_{aO_2} [if $F_{DO_2} < 0.5$]), arterial pH, serum creatinine, serum sodium, serum potassium, hematocrit, and white blood cell count). Additional points are assigned according to the patient's GCS score, the presence of acute renal failure, age, and chronic health status.

At RICU admission, each patient was assigned to the most appropriate diagnostic category among those used by the APACHE II scoring system.[3] Patients without one of these principal diagnoses were included in one of the five categories of organ-system failure or insufficiency (neurologic, cardiovascular, respiratory, gastrointestinal, or renal/metabolic). If the patient was sedated the estimated GCS score before sedation was recorded.

The SAPS II scoring system uses 17 variables: 12 physiologic ones (body temperature, systolic blood pressure, heart rate, respiratory rate, P_{aO_2} [F_{DO_2} if ventilatory assistance is required], serum bicarbonate, blood urea, serum sodium, serum potassium, bilirubin level, urine output, and white blood cell count), age, type of admission (scheduled surgical, unscheduled surgical, or medical), and 3 variables related to underlying diseases: acquired immunodeficiency syndrome, metastatic cancer, and hematologic malignancy.[22]

Statistical Analysis

Comparison of the 2 scores was performed in 2 ways. First, to test for systematic differences among discordant values of the 2 death rates, a generalization of the McNemar test (StatXact-Turbo, Cytel Software Corporation, Cambridge MA) was performed on the contingency table of the 2 death rates, each tabulated in classes of size 10%. This was done to investigate whether one index was systematically greater than the other when they did not agree.

The McNemar test considers only the information contained in discordant observations, so another analysis was performed to assess overall agreement in terms of percent difference between the 2 death rates. However, it must be taken into account that death rate and survival rate (100% minus death rate) play symmetric roles in comparisons because they represent 2 complementary aspects of the same phenomenon. Thus, although the clinical implications are diametrically opposed, the statistical problems posed by a small death rate or a small survival rate (ie, a large death rate) are identical. It is often useful to compute the percent difference between 2 rates with respect to their mean. But the difference between 2 survival rates is numerically the same as the difference between the 2 respective death rates, thus the percent difference should give the same numerical result. So as not to create a fictitiously small percent difference, it is expedient to calculate the percent difference with respect to the smaller of the 2 means: mean death rate or mean survival rate.

We constructed a table with the mean estimated death rate for each admission (in classes of size 10%) against the difference between the 2 estimated death rates in terms of the percent difference with respect to the smaller of the mean death rate or mean survival rate. It was difficult to draw the line between good and unsatisfactory agreement. As an example, we considered agreement to be satisfactory when the percent difference was within 25%.

Empirical receiver operating characteristic (ROC) curves, plotted separately for each index, were intended to illustrate the relationship between the proportion of true-positives (sensitivity) and false-positives (100% minus specificity) and the ability of the 2 scoring systems to discriminate among outcomes.[23]

ROC curves are a generalization of the concept of sensitivity and specificity of a diagnostic test. Because a single threshold value of the diagnostic criterion (here the predicted death rate) may not be representative of the entire prediction procedure, the ROC curve graphs the performance of the procedure for all possible thresholds and thus gives a better picture of how the criterion performs overall, summarized by the area under the ROC curve.

Area under the curve and its standard error were calculated with a spreadsheet according to a procedure using the Wilcoxon-Mann-Whitney statistic.[23] The standard error can be approximated by a formula involving the estimated area under the curve or by a more complex manner using the quantities Q1 or Q2 as defined by Hanley and McNeil.[23] The difference between the 2 areas was estimated and tested using a conservative procedure based on the test described by Henley and McNeil.[24]

Finally, the death rates corresponding to each index, rounded to 4 digits after the decimal point were compared with the outcome for each patient by means of logistic regression, goodness-of-fit being assessed by means of the Hosmer-Lemeshow test,[25] which is considered standard for testing goodness-of-fit in this type of logistic regression model. The calculations were performed with LogXact-Turbo (Cytel Software Corporation, Cambridge MA).

Results

The study cohort features 306 consecutive admissions, mean age 66.5 years (SD 13.7). The average APACHE II score was 17.5 (SD 6.0) and mean predicted death rate for APACHE II was 24.9% (SD 17.2%) as compared with an actual overall RICU mortality rate of 21.6% (Table 1). The average SAPS II score was 39.1 (SD 11.1) and mean predicted death rate for SAPS II was 26.0% (SD 18.4%).

Table 1. Comparison of Mean (SD) Values for Age, APACHE II and SAPS II Scores, Glasgow Coma Scale (GCS) Score, Predicted Risks of Death, and Length of RICU Stay for Survivors and Nonsurvivors.

Variable	All patients (n = 306)	Nonsurvivors (n = 66)	Survivors (n = 240)	p*
Age (years)	66.5 (13.7)	67.0 (13.7)	66.3 (13.7)	0.715
APACHE II Score	17.5 (6.0)	21.3 (6.2)	16.4 (5.5)	<0.0001
SAPS II Score	39.1 (11.1)	46.8 (13.2)	36.9 (9.4)	<0.0001
APACHE II Risk of death (%)	24.9 (17.2)	40.5 (19.6)	20.6 (13.6)	<0.0001
SAPS II Risk of death (%)	26.0 (18.4)	39.4 (22.6)	22.3 (15.1)	<0.0001
GCS	13.5 (2.5)	12.4 (3.2)	13.8 (2.1)	<0.0001
RICU stay (days)†	12 (5, 24)	12 (2, 25)	12.0 (6, 22.5)	0.46
RICU mortality rate (%)	21.6			

* Unpaired *t* test except for RICU stay, which is by unpaired Wilcoxon-Mann-Whitney test.
† Median with quartiles in parentheses.

For 115 patients (38%) the corresponding death rates agreed within 25% of the smaller of the mean death rate and mean survival rate (Fig. 1). Grouping the death rates in classes of 10%, we found close agreement in 140 admissions (46%) (Table 2). No systematic trend towards unidirectional

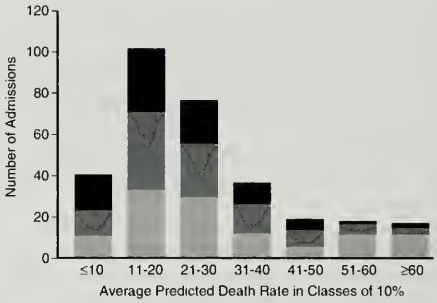

Fig. 1. Agreement of death rates eslimated from APACHE II and SAPS II. The estimated death rates are grouped in classes of 10%. Percent difference with respect to the smaller of the mean death rate or mean survival rate is depicted by ■ indicating above +25%, ■ indicating between −25% and +25%, and ■ indicating below −25%.

Table 2. Death Rate Estimated from APACHE II and SAPS II, Cross-Tabulated in Classes of 10%. Close Agreement Is Found in the 140 Admissions along the Main Diagonal (Bold Face). The Table Shows the Number of Patients in Each Category.

		SAPS II Risk of death (%)					
		<10	<20	<30	<40	≥40	Total
APACHE II Risk of Death (%)	<10	**29**	17	5	2	1	54
	<20	14	**49**	26	14	1	104
	<30	3	19	**15**	9	4	50
	<40	0	12	15	**12**	9	48
	≥40	1	2	5	7	**35**	50
	Total	47	99	66	44	50	306

disagreement was found with the generalization of the McNemar test.

The ratio between the actual and predicted hospital mortality (known as the standardized mortality ratio),[26] proposed as a valid measure for quality of care and performance of specific ICUs, is 86% for APACHE II and 83% for SAPS II (values less than 100% indicate a lower mortality rate than predicted).

Stay in RICU ranged from 1 to 225 days, with a mean duration of 19.8 days (SD 28.2); the median value was 12 days for both survivors and nonsurvivors. The difference in the RICU stay between survivors and nonsurvivors did not reach statistical significance (p = 0.46 by the unpaired Mann-Whitney-Wilcoxon test). Approximately 46% of patients in both groups stayed in the RICU no longer than 10 days.

Figure 2 illustrates the predicted risk of death determined by the APACHE II score, according to the patient's medical or surgical status. There were only 20 postoperative patients, because our RICU admits patients with primarily chronic respiratory insufficiency due to chronic obstructive pulmonary

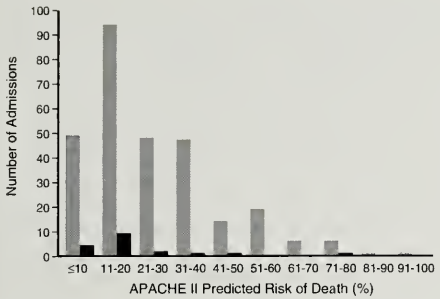

Fig. 2. Distribution of APACHE-II-predicted risk of death for the 306 consecutive RICU admissions (286 nonsurgical and 20 postoperative)

disease (COPD), kyphoscoliosis, and neuromuscular and chest-wall disorders during a relapse of their disease resulting in acute respiratory failure. Only a few patients were admitted for observation and monitoring of vital signs.

Table 3 illustrates the characteristics and the diagnostic categories of 306 consecutive admissions in our RICU for different diagnoses. More than half of the admissions were due to COPD.

Table 3. Characteristics and Diagnostic Categories for the 306 Consecutively Admitted Respiratory Intensive Care Unit Patients.

Admissions	306
Gender	
Men	195
Women	111
Diagnostic Categories	
Nonsurgical	286
Chronic obstructive pulmonary disease	179
Neuromuscular and chest-wall diseases	37
Infections	20
Neoplasm	10
Congestive heart failure	21
Pulmonary edema (noncardiogenic)	1
Postcardiac arrest	3
Postrespiratory arrest	2
Status asthmaticus	5
Sepsis	1
Metabolic-renal	1
Others	6
Surgical	20
Heart valve surgery	1
Thoracic surgery for neoplasm	6
Respiratory failure after surgery	5
Gastrointestinal surgery for neoplasm	3
Others	5

The mean APACHE II score of survivors was 16.4 (SD 5.5) while the mean for nonsurvivors was 21.3 (SD 6.2) ($p < 0.0001$ by the unpaired t test). For the SAPS II system, the mean score of survivors was 36.9 (SD 9.4), while that for nonsurvivors was 46.8 (SD 13.2) ($p < 0.0001$). In addition, mean predicted risks of RICU mortality were significantly lower ($p < 0.0001$) for survivors than nonsurvivors using both scores (Table 1).

The mean best 24-hour GCS score at the time of admission was 12.4 (SD 3.2) for nonsurvivors and 13.8 (SD, 2.1) for survivors ($p < 0.0001$).

On average, the APACHE-II-predicted risk of death was closer to observed RICU mortality than the SAPS-II-predicted risk, although, on average, both were smaller than the observed average risk. Figure 3 shows the relationship between predicted risk of death and observed RICU mortality for both scores.

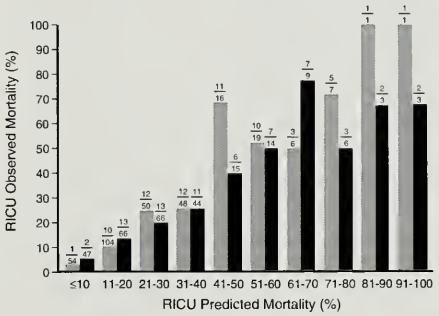

Fig. 3. Observed RICU mortality in the 306 patients grouped according to mortality predicted by APACHE II (▭) and SAPS II (■). Because predicted mortality is different for the 2 indices, the number of deaths and admissions in each group is indicated above the bar. The observed mortality should be compared with the midpoint of each predicted mortality class; 5% for the ≤ 10% group, and so on.

Area under the APACHE II empirical ROC curve was 80.88% with a standard error (SE) 2.89%, larger than that found for SAPS II: 73.52%, SE = 3.61% (Fig. 4), indicating better predictive ability of APACHE II. SE for the APACHE II ROC curve area was much smaller using Q1 and Q2 than the estimate based only on the area (3.40%). To test the difference between the areas corresponding to APACHE II and SAPS II, an estimate of the common SE under the null hypothesis (3.6%) was calculated from the common area (77.2%). Prediction with APACHE II was found to be significantly better ($p < 0.01$) with this conservative test.

Table 4 shows the classification matrices for the two methods calculated from the 2×2 tables using different decision criteria (40%, 50%, 70%). For each decision criterion, the sensitivity (the proportion of the observed deaths that were cor-

Table 4. Classification Matrices for APACHE II and SAPS II Using Decision Criteria of 40%, 50%, and 70%.

	APACHE II Predicted Alive	APACHE II Predicted Dead	SAPS II Predicted Alive	SAPS II Predicted Dead	Total
40% Decision Criterion					
Observed alive	221	19	217	23	240
Observed dead	35	31	39	27	66
Total	256	50	256	50	306
50% Decision Criterion					
Observed alive	226	14	226	14	240
Observed dead	46	20	45	21	66
Total	272	34	271	35	306
70% Decision Criterion					
Observed alive	238	2	235	5	240
Observed dead	59	7	59	7	66
Total	297	9	294	12	306

Decision Criterion	SCORE	Sensitivity	Specificity	PPVD	PPVS	TCCR
40%	APACHE II	47%	92%	62%	86%	82%
	SAPS II	41%	90%	54%	85%	80%
50%	APACHE II	30%	94%	59%	83%	80%
	SAPS II	32%	94%	60%	83%	81%
70%	APACHE II	11%	99%	78%	80%	80%
	SAPS II	11%	98%	58%	80%	79%

		Actual Outcome	
		NS	S
Predicted Outcome	NS	A	B
	S	C	D

Sensitivity = A/(A + C); Specificity = D/(B + D); Positive predictive value for dying (PPVD) = A/(A + B); Positive predictive value for surviving (PPVS) = D/(D + C); Total correct classification rate (TCCR) = (A + D)/(A + B + C + D); NS = nonsurvivors; S = survivors.

rectly predicted), the specificity (the proportion of observed survivors correctly predicted to survive), the positive predictive value for dying, the positive predictive value for surviving and, finally, the overall correct classification rate (proportion of patients correctly classified as survivors or nonsurvivors) are reported.

Applying decision criteria at 5% intervals, we found the best overall correct classification rate for APACHE II to be 82% at cut-off point of 40%. Instead, that for SAPS II was 81% at cut-off point of 50% (both shown in Table 4).

χ^2 for the Hosmer-Lemeshow goodness-of-fit test statistic for APACHE II was 7.37 with 7 degrees of freedom ($p = 0.39$; acceptable but not excellent fit), whereas for SAPS II it was 14.84 with 7 degrees of freedom ($p = 0.038$; inadequate fit).

Discussion

The APACHE II and SAPS II scoring systems are widely accepted indices to describe the severity of illness, to establish the individual prognosis, and to group adult ICU patients by predicted risk of mortality. In addition, these scores, as other authors have proposed, can be used to detect and/or compare the quality of care in different ICUs[27] and, in this sense, are considered multipurpose.[28]

In this study, both APACHE II and SAPS II yielded average death rates larger than the empirical one, indicating that the RICU was functioning well during the observation period.

The Hosmer-Lemeshow test indicated adequate but not exceptional goodness of fit for APACHE II; whereas, for SAPS

II, the test suggested a significant difference between the distributions of observed and expected death rates. The area under the ROC curve was significantly higher for APACHE II.

Agreement between the two scores was better with respect to the whole group than for individual admissions. However the disagreement for individual admissions did not seem to be one-sided, as seen from the generalization of McNemar test. The superiority of APACHE II in our respiratory patients is not surprising because of the items it contains regarding specific pathologies, whereas SAPS II may well be more useful in a general ICU.

The predictive value of the APACHE II score in our RICU patients (with a correct classification rate of 82%) is similar to that reported by other studies performed in multidisciplinary or surgical ICUs.[3,11,18] Therefore our analysis indicates that APACHE II score is a good predictor of hospital outcome in our population of patients with respiratory disease.

The average RICU stay in our study (19.8 days) was longer than that reported in generalized or surgical ICUs.[11,15] This fact reflects the peculiarity of our RICU, which admits principally patients with chronic respiratory disorders (eg, COPD, bronchiectasis) or neuromuscular diseases during an acute relapse. The underlying chronic respiratory insufficiency induces additional problems that can lengthen the course of the acute illness and make the weaning process after intubation more difficult.[29]

We conclude that the APACHE II scoring system can be used to describe and stratify our respiratory patients by the severity of their illness with greater confidence than SAPS II.

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The Effect of Pulmonary Secretions on Respiratory Mechanics in Intubated Patients

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BACKGROUND: The effect of airway secretions on respiratory mechanics in adult, mechanically ventilated patients has not been reported. We sought to determine whether such an effect existed using a prospective, nonrandomized cohort of medical- and surgical-intensive-care-unit patients. METHODS: Thirty mechanically ventilated patients with increased airways resistance (R_{aw} ≥ 15 cm $H_2O \cdot s \cdot L^{-1}$) were enrolled. Peak ($P_{peak}$) and end-expiratory pressures (P_{pause}) were recorded before and after routine standardized endotracheal suctioning was performed (vacuum = −120 torr and 2 passes of the suction catheter separated by 1 minute). R_{aw} and respiratory system compliance (C_{rs}) were calculated. Mean R_{aw} and mean C_{rs} were compared before and after suctioning using paired *t* tests. RESULTS: Suctioning reduced R_{aw} in 27 of 30 patients from a mean (SD) of 24.8 (7.9) to 22.1 (5.5) cm $H_2O \cdot s \cdot L^{-1}$, $p < 0.01$). Of 30 patients, 11 experienced ≤ 1 cm $H_2O \cdot s \cdot L^{-1}$ reduction in R_{aw} after suctioning and, when a single patient who had an unusually high reduction in resistive pressure is excluded, R_{aw} decreased in the remaining patients from 23.5 (5.0) to 21.6 (5.2) cm $H_2O \cdot s \cdot L^{-1}$ ($p = 0.15$). There was no significant change in C_{rs} following suctioning. CONCLUSION: Airway secretions are a relatively small component of increased R_{aw} in our critically ill patients. However, some patients may experience marked reduction in R_{aw} with endotracheal suctioning. Further studies may help identify patients who are most likely to benefit from this therapy. [Respir Care 1995;40(10):1048-1051]

Background

Endotracheal suctioning is performed routinely in the management of intubated, mechanically ventilated patients. Several studies have examined the complications and hemodynamic effects of endotracheal suctioning,[1-3] but no studies have assessed the effects of suctioning on respiratory system mechanics in adults. Airway secretions can contribute to airways resistance (R_{aw}) by reducing the diameter of the airway lumen and by creating turbulent flow patterns. In this study we assessed the effects of endotracheal suctioning on R_{aw} and respiratory system compliance (C_{rs}) in intubated mechanically ventilated patients.

Methods

Our hospital investigational review board waived review of this observational study. Patients admitted to the intensive care unit between September 1993 and March 1994 who required mechanical ventilation (Model 7200, Puritan-Bennett Corp, Overland Park KS) and who had a resistive airway pressure (P_R) ≥ 15 cm H_2O (Peak pressure [P_{peak}]–end inspiratory pause pressure [P_{pause}]) were included in this study. Patients were excluded if they had received aerosolized bronchodilators

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or suctioning within 2 hours of study. All patients had 7- or 8-mm oral endotracheal tubes (ETT) in place and were heavily sedated so that < 5 breaths/min were patient-triggered.

Open endotracheal suctioning was performed by the bedside nurse who instilled 3 mL normal saline followed by 2 passes of the suction catheter (14 Fr, Superior Healthcare Group, Cumberland RI) separated by one minute. A vacuum pressure of −120 torr was used for suctioning. Tidal volumes were delivered using a constant (square wave) inspiratory flow of 60 L/min. Inspiratory flow was assumed equal to the set flow for purposes of R_{aw} calculation (P_R/set flow). Machine self tests were performed at least every 5 days. Tidal volumes and airway pressures were recorded from the digital display of the ventilator. Static airway pressures were determined on the first breath after application of a 1 second end-inspiratory pause generated by the ventilator. Both pre- and post-suctioning airway pressure observations were made while the patients were in the supine position. Three measurements of P_{peak} and P_{pause} were performed pre- and post-suctioning, at one minute intervals and averaged. P_R and C_{rs} were calculated.[4]

$$C_{rs} = \frac{V_T}{P_{pause} - \text{set-PEEP}},$$

where PEEP = positive end-expiratory pressure.

P_R is the numerical equivalent of R_{aw} because

$$P_R \cdot 60\ \text{L/min} \cdot 1\ \text{min}/60\ \text{s} = R_{aw}.$$

Because patients were not muscle relaxed, intrinsic PEEP was not measured and, therefore, not included in the computation of C_{rs}.

Pre- and post-suctioning R_{aw} and C_{rs} were compared using paired *t* tests. Statistical significance was set at $p < 0.05$.

Results

Thirty patients, whose characteristics are listed in Table 1, were enrolled in this study. Initial R_{aw} ranged from 15.2 to 58.0 cm $H_2O \cdot s \cdot L^{-1}$ with a mean (SD) value of 24.8 (7.9)

Table 1. Profiles of 30 Sedated, Mechanically Ventilated Patients Who Underwent Endotracheal Suctioning

#	Age	Gender*	Rate/Tidal Volume	Diseases†	RF Type‡	Pre-Suctioning P_R§	Post-Suctioning P_R
1	75	F	10/600	Pulmonary fibrosis, pneumonia	1	24.5	20.8
2	83	F	10/600	CHF	1	24.4	24.0
3	75	F	10/500	Esophageal CA, COPD	2	24.5	18.6
4	81	F	12/550	COPD, CHF	1	22.5	19.8
5	77	F	12/600	COPD, Hip fracture	3	20.9	20.2
6	82	M	10/600	COPD, pneumonia	1	22.0	18.5
7	56	M	12/800	CRF, CAD, post-CABG	3	15.2	14.3
8	63	F	12/800	CAD, post-CABG	3	30.4	29.3
9	55	F	12/480	COPD	2	21.7	19.5
10	70	F	14/700	COPD	2	20.2	16.4
11	69	F	10/600	COPD, CHF	1	19.6	17.8
12	40	F	15/500	Asthma	2	23.3	25.5
13	70	F	12/700	CHF	1	16.5	16.1
14	62	F	12/650	CAD, COPD	1	17.8	19.4
15	60	F	20/500	Pneumonia	1	27.0	23.4
16	76	M	12/750	AAA resection	3	21.0	16.1
17	44	F	34/500	GI bleed	1	24.8	24.7
18	60	F	15/550	COPD, pneumonia	1	22.6	23.1
19	74	F	26/400	COPD, aspiration pneumonia	1	29.7	29.1
20	75	F	10/600	Colon CA, post-colectomy	3	20.2	20.1
21	76	M	10/750	CAD, post-nephrectomy	3	20.4	18.8
22	40	F	10/550	Asthma, CRF, sepsis	2	24.8	21.8
23	61	F	12/450	COPD	2	31.2	28.0
24	31	M	10/800	Gunshot wounds	3	24.1	20.0
25	32	M	22/500	Asthma	2	38.7	37.4
26	30	M	20/500	Asthma	2	58.0	32.0
27	75	F	20/550	COPD, pneumonia	1	24.4	23.4
28	54	F	12/430	Asthma	2	31.7	29.4
29	73	F	10/600	Pulmonary embolus	1	20.2	18.2
30	65	M	10/550	COPD, pneumonia	2	20.0	14.5

* Gender: F = female and M = male

† Diseases: CHF = congestive heart failure, CA = carcinoma, CRF = chronic renal failure, CAD = coronary artery disease, CABG = coronary artery bypass graft, AAA = abdominal aortic aneurysm, GI = gastrointestinal, COPD = chronic obstructive pulmonary disease

‡ respiratory failure type (RF Type) 1 = hypoxemic respiratory failure, 2 = ventilatory failure, 3 = perioperative respiratory failure

§ P_R = resistive airway pressure (cm H_2O)

cm $H_2O \cdot s \cdot L^{-1}$. Endotracheal suctioning reduced R_{aw} in 27 of 30 patients causing a groupwise mean (SD) to fall from 24.8 (7.9) to 22.1 (5.5) cm $H_2O \cdot s \cdot L^{-1}$ ($p < 0.01$). The magnitude of the reduction in resistance with suctioning correlated with the magnitude of the presuctioning R_{aw} but the difference was not significant if the evident outlier, patient #26, is excluded ($p > 0.05$). If Patient #26 whose R_{aw} fell 26 cm $H_2O \cdot s \cdot L^{-1}$ is excluded from the analysis, R_{aw} only decreased from 23.5 (5.0) to 21.6 (5.2) cm $H_2O \cdot s \cdot L^{-1}$ ($p = 0.15$). The reductions in R_{aw} were similar in patients with and without chronic obstructive pulmonary disease ($p > 0.1$). Three patients (Patient #12, 14, and 18) experienced a mild increase in R_{aw} after suctioning. Mean (SD) C_{rs} was 34.9 (13.5) mL/cm H_2O before suctioning and 34.5 (13.6) mL/ cm H_2O after suctioning ($p = 0.7$). No adverse patient events due to endotracheal suctioning were noted.

Discussion

Our results demonstrate that endotracheal suctioning reduces inspiratory resistance in intubated patients with moderate to severe airways obstruction. Airways secretions increased patient-ventilator circuit resistance by an average of 12.2% above that level seen after suctioning. Note that if one patient who experienced a 26 cm $H_2O \cdot s \cdot L^{-1}$ reduction in resistance is excluded, the observed reduction in our sample of patients *does not* reach statistical significance. However, the trend implies that secretions increase R_{aw}—a conclusion that makes physiologic sense. Because suctioning does not remove all secretions, the reduction that we observed likely underestimates the total contribution of secretions to R_{aw}. Insofar as secretions increase R_{aw} they increase work of breathing, may contribute to the pathogenesis of respiratory failure, and may hinder liberation from mechanical ventilation in some patients.

In the intubated, mechanically ventilated patient, resistive mechanical load is comprised of both the resistance posed by the patient's airways and by the ventilator circuit. Ventilator-circuit resistance includes resistances from: conducting tubing,[5] humidifiers,[6,7] and the endotracheal tube.[8] ETT resistance may increase because of luminal secretions, tube deformation and changes in head/neck position.[9] In previous studies, we demonstrated that one reversible component of increased R_{aw} is bronchospasm.[10-12] Our current study points out another determinant of R_{aw}, which has not been previously demonstrated in adult patients. A limitation of this study is that we did not measure tracheal pressure, which would have allowed us to partition the reduction in R_{aw} between endotracheal tube and patient airways.[9]

We noted wide variation in the effect of suctioning on patient-ventilator resistances, ranging from an increase of 10% to a decrease of 45%. Because many factors contribute to resistance, a broad heterogeneity of responses is not surprising. Note that patients #1, 3, 10, 26, and 30 arguably experienced clinically important reductions in R_{aw} with suctioning whereas, suctioning was followed by small *increases* in R_{aw} in patients #12, 14, and 18.

We did not seek to identify the patients most likely to benefit from endotracheal suctioning, but a recent study suggests that a physiologically meaningful volume of secretions may be detectable by examination of the pressure-volume loops of sedated, mechanically ventilated patients—the characteristic sawtooth pattern may help identify patients who are most likely to benefit from suctioning.[13] In addition, the presence of secretions visible in the upper airway may also signal patients likely to benefit from suctioning; patient #26, whose R_{aw} decreased by 26 cm $H_2O \cdot s \cdot L^{-1}$, had copious secretions visible in the proximal endotracheal tube prior to suctioning.

Because airway secretions are a reversible cause of increased R_{aw}, endotracheal suctioning should be considered in the initial clinical approach to patients with elevated P_R. When suctioning alone reduces resistance to less than 10 cm $H_2O \cdot s \cdot L^{-1}$, bronchodilators and steroids, may be unnecessary.[9-12] When therapeutic aerosols are indicated, prior removal of airway secretions may enhance delivery of aerosol particles to the distal airways. Kim and Eldridge[14] demonstrated that a straight mucus-lined glass tube (10 mm diameter, 20 cm length) trapped up to 98% of 5.0 μm MMAD (mass median aerodynamic diameter) aerosolized particles, whereas a dry tube trapped less than 1%. Accordingly, clinical studies designed to examine the effects of therapies on R_{aw} should control for airway secretions—suctioning should be performed prior to any intervention.

The viscoelastic properties and the transport characteristics of tracheobronchial secretions are under the control of a variety of neural-humoral and inflammatory mediators.[15] Endotracheal intubation impairs the normal mechanisms of secretions clearance (expectoration), and the presence of an ETT may increase the production of secretions.[16] Inflammation, infection, dehydration, and medications may also contribute to altered mucociliary function.

Endotracheal suctioning is the most commonly used method of removing endotracheal secretions in patients on mechanical ventilation. Even though suctioning is considered to be a benign procedure, it can adversely alter blood flow and gas exchange[1,3] and may be associated with complications such as hypotension, arrhythmias,[17] and death.[18] Hyperventilation and hyperoxygenation prior to suctioning appear to minimize these risks.[19] Suctioning can provoke bronchospasm in some patients.

Beyond suctioning (mechanical elimination of secretions), a number of agents have been proposed to reduce airways mucus production or to improve clearance. These include mucolytics (eg, N-acetylcysteine and bromhexine), enzymes (eg, trypsin and deoxyribonuclease), detergents (eg, tyloxapol), and expectorants (eg, iodinated glycerol). Glucocorticosteroids, antihistamines, and anticholinergics also affect mucociliary function.[20-22] Aerosolized recombinant human deoxyribonu-

clease (dornase alfa) is the only agent which has been shown to be effective (only in patients with cystic fibrosis).[23] Clinical experience with mucolytics and bland aerosols in non-intubated patients with chronic obstructive lung disease has been disappointing.[24] Moreover, bronchospasm is a common complication following the use of aerosolized normal saline or mucolytics, necessitating the concomitant use of bronchodilators.[25-27] β-2 agonists,[28] high-frequency chest-wall oscillation,[29] and rehydration[30] have been shown to stimulate mucociliary clearance. However, the clinical efficacy of these interventions regarding secretion clearance and pulmonary mechanics is uncertain. In cases of excessive secretions with and without plugging and atelectasis, therapeutic fiberoptic bronchoscopy may be useful in removing retained secretions and mucus plugs,[31] and may ameliorate airways obstruction and dyspnea in select patients.[32] Endotracheal suctioning, however, remains the most commonly employed clinical approach to clearing airways secretions in intubated mechanically ventilated patients.

In conclusion, this study demonstrates a modest reduction of R_{aw} after endotracheal suctioning in a population of mechanically ventilated adults with increased R_{aw}. Further studies may help identify patients most likely to benefit from suctioning and elucidate the optimal frequency and timing of endotracheal suctioning, thus reducing the risks and maximizing the benefits of this therapy.

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Selecting Students for a Baccalaureate-Degree Respiratory Care Program

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BACKGROUND: This study sought to establish a defensible method for selecting students into our respiratory care program and to extend what we know about student-selection models. METHODS: Respiratory care students from 7 classes were included (n = 74). We analyzed relationships between predictor variables and two entry-level outcomes—students' grade-point average from the first 3 semesters of respiratory care courses (3S-RCGPA) and their scores (%) on the CRTT self-assessment examination (CSAE). Predictor variables were: AGE, GENDER, preprofessional college CREDITS, preprofessional OFF-CAMPUS credits (percent of CREDITS), ACT (American College Test) scores, presence or absence of an ACT score, preprofessional GPA (PPGPA), science-and-quantitative GPA (SQGPA), PPGPA-SQGPA difference (DGPA), TIME from the present, class SIZE, and INTERVIEW scores. Pearson correlations, bivariate scatter plots, and descriptive statistics were used to screen variables. Some predictors were transformed or downgraded (to categorical variables) for multivariate analyses, which included multiple regression and multivariate analysis of variance (MANOVA). RESULTS: 3S-RCGPA correlated moderately with CSAE. PPGPA and ACT composite scores were significant multiple correlates with 3S-RCGPA and CSAE ($p < 0.05$). Because of overlapping variances with PPGPA and ACT, CREDITS, DGPA, and INTERVIEW were not significant multiple correlates with either outcome measure ($p > 0.05$). Students who took all their preprofessional courses on-campus tended to have significantly higher 3S-RCGPA and CSAE values than students who took preprofessional courses off-campus ($p < 0.05$). AGE, GENDER, TIME, ACT, and SIZE groups had statistically similar average 3S-RCGPAs and CSAEs. CONCLUSIONS: Ranking candidates based on predicted 3S-RCGPA and CSAE is justified because it helps select students who are most likely to achieve entry-level status—readiness to sit the CRTT examination—after 3 semesters of respiratory care courses. [Respir Care 1995;40(10):1052-1062]

Introduction

In this study we sought to increase our understanding of criteria used to select students for our baccalaureate-degree respiratory care program and to extend what is generally known about selecting students for similar programs. Interest in how we selected our students increased after reviewing the work of Op't Holt and Dunlevy.[1] Understanding that their results were limited to their program, these authors recommended that others attempt to duplicate and extend the study for their own programs.

Our 4-year program is located in a midwestern, Carnegie-Research-I university. Preprofessional students spend the first 2 years completing general education courses, after which they apply to our respiratory care program for the 2 years of professional curriculum. Graduates receive only a baccalaureate degree; participants do not receive an associate degree.

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Neither do our students challenge the entry-level examination (Certified Respiratory Therapy Technician [CRTT][2]) until they have graduated. Our purpose is to prepare advanced respiratory care practitioners at the baccalaureate level.

Entry-level outcomes are important to us because we use entry-level performance to indicate whether our students are progressing as they should. Specifically, we believe that after 3 semesters in the program (after the Junior year is completed), our students have achieved entry-level status, and it is appropriate to measure the magnitude of that achievement. Because we have been measuring our students' entry-level performance for some time and because we *require* that they pass the CRTT self-assessment examination (CSAE), we believed it reasonable to use entry-level outcomes as criteria against which our selection variables could be compared.

Expanding on Op't Holt & Dunlevy

Op't Holt and Dunlevy[1] reviewed the literature of the 1980s in preparation for their study. Therefore, we limited our literature review to the 1990s and found that the unexplained variation in measures of success ranged from a low of 25%[3] in one health-professions program to a high of 86%[4] in another, with a median unexplained variation of 54%.[5] This confirmed our belief that although we may come to know more about why students do well in our program, perfect prediction is an unattainable goal. We anticipated that a noticeable portion of variation in academic achievement would remain unexplained, even if we could explain a large portion of the variation in entry-level achievement. Therefore, we conducted this study to verify that we were selecting students rationally and to suggest ways that might add to the explanatory power of our selection model.

Departing from Op't Holt & Dunlevy

Evidence from McGaghie[6] helped affirm our assumptions. McGaghie[6] suggested that because prediction of human behavior will always be imperfect, prediction and selection decisions need not be synonymous. This caused us to conclude that while we in part wanted to duplicate and extend the work of Op't Holt and Dunlevy,[1] our goals differed. Whereas Op't Holt and Dunlevy[1] sought to confirm that they could reasonably predict performance and thereby screen out candidates with low likelihood of success, we sought to predict which students could be expected to have academic success. This divergence of purpose was further encouraged by McGaghie[6] who reminded us that "grades predict grades, test scores predict test scores, ratings predict ratings, but attempts to demonstrate scientific convergence among such indicators of professional competence have not been successful." Though McGaghie[6] seems to suggest that near-perfect prediction should be the criterion for adopting a selection model, our goals were not set so high. We conducted this study to improve how we select students and hoped our results could serve as a second model for other programs to follow, should they seek to better understand their own selection methods.

Looking for Variables Worth Studying

The literature review helped produce a list of potential outcomes or dependent variables.[7-13] Two broad categories of these are typically at issue: (1) success in the professional program usually manifested by grade-point average (GPA) and graduation or (2) success on an external measure of professional competence, such as a standardized examination. Standardized examination scores that have been analyzed as potential correlates with success predictors include: The Modified Hill Cognitive Style Model (MHCSM),[4] American College Test (ACT),[3,8,10] Scholastic Aptitude Test (SAT),[7,8] Health Occupations Aptitude Examination (HOAE),[8] Stanford Diagnostic Reading Test,[9] Otis Quick Scoring Mental Ability Tests (OTIS),[9] Lengacher Role Strain Inventory,[10] nursing ACT-Proficiency Examination Program (PEP) test,[11] Optometry College Admission Tests (OCAT),[12] California Personality Inventory (CPI)[12] and the New South Wales Higher School Certificate (HSC).[13] Among these standardized measures, the MHCSM,[4] SAT,[7] HOAE-Vocational Adjustment,[8] OTIS,[9] ACT,[10] ACT-PEP,[11] OCAT-verbal and -quantitative scores,[12] CPI,[12] and HSC-English scores[13] have provided substantial explanation of variance on measures of academic success.

ACT subscores in Social Science, Natural Science, Mathematics, and English have failed to provide substantial explanation[3,10] whereas the composite ACT score was a significant correlate with success in the study by Lengecher and Keller.[10] Another finding was that verbal and language abilities seemed to play a predictive role among students in optometry for whom English was a second language[12] and among medical students.[13] The MHCSM also measured some language constructs. A study using MHCSM found that nursing students achieved a better match with their educational environment and tended to have higher final grades when they favored visual learning, solving problems independently, and using logical-deductive reasoning.[4]

Several variations on GPA have served as predictor variables in many studies[1,3,4,7-10] and have also been used as a dependent variable.[1,4,8,11-13] Other dependent variables included medical college aptitude test (MCAT) scores[7] and scores from the National Council Licensure Examination for Registered Nurses (NCLEX-RN).[3,5,10] Other examples of interval-level data analyzed as potential predictors included: interview scores,[1,8,9,14] age,[3,8-11,13] grades in individual courses,[5,10] years since high school,[8] high school quartile class rank,[8] number of college credits,[8,9] essay evaluations,[9,15] academic competitiveness of undergraduate institutions,[12] hours spent playing sports, and hours spent studying.[13] Among these, the following were found to significantly correlate with measures of success. Interview scores were found to correlate only with

field-work evaluations among occupational therapy students[14] but had no multivariate relationships with academic success.[1,8,9,14] Age was related with success measures in baccalaureate-degree nursing[3] and medical school[13] programs but was found to be an insignificant multiple correlate in 4 other studies.[8-11] Grades from individual courses predicted success in 2 nursing programs.[5,10] High school class rank (quartile) correlated with program performance, whereas years since high school predicted clinical performance in a nontraditional respiratory care program.[8] Essay evaluations predicted success among occupational therapy students[9] but were not helpful in making selection decisions among physical therapy students.[15] The academic competitiveness of undergraduate institutions attended by optometry candidates of minority races was found to systematically differ between those who dropped out and those who graduated.[12]

Nominal- and ordinal-level data analyzed as correlates with success included: student transfer/nontransfer status,[3,7] gender,[3,9,11] minority/majority status,[7,9,11,12] having children,[8] having previous college experience,[8] marital status,[8,9] full- or part-time student status,[11] employment status,[8,11,13] leadership roles and involvement in music, drama, debate, and student council,[13] whether English was the students' first language,[13] and whether students were natives of the country in which the school was located.[13] Minority Asian optometry students were found to have lower OCAT-verbal scores and CPI scores than their majority counterparts but similar GPAs, while in the program.[12] Black and Hispanic optometry students had lower preoptometry GPAs, lower OCAT-Physics and OCAT-Quantitative scores, lower CPI scores, and lower GPAs than their majority counterparts while in the optometry program.[12] CPI scores were supposed to reflect "such positive traits of personality as responsibility, flexibility, tolerance, and intellectual efficiency."[12] Prior participation in debate, having English as a first language, leadership experience, and completing higher education in Australia (a native effect) was found to predict success among Australian medical students.[13]

These studies represent wide geographic sampling including the states of Missouri,[3,4] Minnesota,[5] Florida,[7,10] Iowa,[11] and Texas,[8,9,12] as well as Ontario, Canada[14] and Australia.[13] Several health-related professional populations were represented including: respiratory therapists,[1,8] medical students,[7,13] occupational therapists,[9,14] physician assistants,[9] physical therapists,[9,15] baccalaureate-degree,[3,5,11] associate-degree[10] and diploma-seeking nurses,[4] and optometrists.[12] The sample sizes were adequate for the most part though Posthuma and Noh's[14] sample of 32 may have offered insufficient statistical power to detect a significant difference between group means. The remaining studies with significant findings enrolled 40-2,600 subjects. Five of the studies[5,7,9,10,13] had more than 100 subjects and four[3,4,11,12] had more than 300 subjects.

Two studies involving baccalaureate-degree nursing programs recommended purposeful examination of progress after students' Junior year to identify those who were having academic problems.[3,5] Mills et al[3] found that their model was more sensitive in identifying academic success than it was specific for predicting failure, yet they recommended the end of the Junior year as the best time to intervene to successfully remediate students on a course to fail. Heupel[5] also found that nursing students' Junior year GPA was the second strongest multiple correlate among 3 course grades in a multiple regression model designed to predict registered-nurse-licensing-examination scores.

Variable Descriptions

Because many of these studies used GPA and standard-examination scores as dependent variables, we used the students' GPA from the first three semesters in the respiratory care program (3S-RCGPA) and CSAE scores (% correct) as dependent variables. 3S-RCGPA is a reflection of the students' Junior-year achievement and it includes grades from their first year of respiratory care courses. After the first 3 semesters, the students were administered the CSAE because we believed that they should have achieved entry-level status and that CSAE was a reasonable means of assessing that status. Students who failed were required to retake other versions of the examination until they did pass. However, our CSAE measures for this study were taken from the first administration of the examination.

Traditionally, our selections have been based on preprofessional GPA (PPGPA), science GPA, ACT scores (when available) and an INTERVIEW score. At one level, we sought to find whether aspects of our existing selection methods were reasonable. Given the information described in the other studies, we also wanted to evaluate other potential predictors that might provide still more information about student performance in our program. Extending Op't Holt and Dunlevy's[1] method, we created a science-and-quantitative GPA (SQGPA) variable. SQGPA included preprofessional science, math, and other quantitatively oriented courses, such as statistics. Because differential performance in general courses versus those with a science and quantitative orientation may be related to entry-level success, we created yet another variable—the PPGPA-SQGPA difference (DGPA). We found no basis in the literature for considering this variable, yet, for us, the question was compelling.

We wondered whether academic performance might vary with the number of college credits and included preprofessional college credits earned (CREDITS) as a predictor. Because of the 'native' effect demonstrated in Parker's[13] study, we separated preprofessional CREDITS to isolate those earned off campus as a proportion of CREDITS (OFF-CAMPUS) to see whether entry-level outcomes varied systematically with credit earned off-campus. The study covered 7 years. Therefore, we also used time (TIME = 1996 − graduation year) in our model. While examining TIME, we discovered that earlier classes tended to have fewer students. The size of each class was 5-16. Therefore, we added class size (SIZE) to our list of predictors.

Completing the list of potential predictors were GENDER, AGE at application, and ACT composite scores. GENDER and AGE were studied in part because other investigators[3,8-11,13] have used them as independent variables with varying results. Even if variation in performance was evident based on these variables, we could not exclude students on the basis of GENDER and AGE. However, because ours is a model to aid in the decision to include individual students, their inclusion was justified. ACT scores have an established history of predicting Freshmen year GPA, so its inclusion in models designed to test Junior year performance in a specialized curriculum such as respiratory care's is unique. However, given that ACT is a general academic measure and that acquiring entry-level status must tap some general academic skills, we wondered whether ACT retained predictive power so far into our students' college careers.

Screening & Refining the Variables

Because multiple dependent and independent variables had become evident, multivariate statistical models were required. Because multivariate statistical tests are weakened by data that violate the assumptions made by the models, the data must first be screened.* If two potential predictors shared substantial variation then multivariate analysis using both variables would suffer diminished (1) power to find a difference and (2) efficiency caused by introducing redundancy into the model. We decided to determine whether any independent variables were so strongly correlated with one another that they should not be used together. This allowed us to construct our multivariate model using only the independent variable possessing the stronger correlation with the dependent variables, without weakening those relationships.

Linear multivariate models also require that the data be normally distributed and that potential predictors be linearly related to the dependent variables. Failing normality or linearity, data can be square-root or logarithm transformed and, depending on the skew of the data, the values of the variable can be reduced by a constant.[16] At times, data can be so nonnormally distributed and so nonlinear that transformation is not successful. In such cases, data may be downgraded to the ordinal or nominal level and analyzed using groupwise comparisons of means. AGE, OFF-CAMPUS, TIME and SIZE required downgrading.

Null Hypotheses (H_o)

To determine whether 3S-RCGPA was representative of successfully reaching entry-level status and, therefore, a viable dependent variable, we posed

H_o1: 3S-RCGPA is not significantly related to CSAE.

Because we were reasonably confident that 3S-RCGPA was a viable entry-level measure, we tentatively included 3S-RCGPA in the remaining hypotheses. However, should we accept H_o1, 3S-RCGPA will be withheld from further analyses.

A significant group of students had no ACT score, limiting the sample size for any analyses involving ACT. Therefore, we posed

H_o2 (a): Neither ACT, PPGPA, SQGPA, DGPA, CREDITS, or INTERVIEW is significantly correlated with 3S-RCGPA for students with ACT scores.

(b): Neither ACT, PPGPA, SQGPA, DGPA, CREDITS or INTERVIEW is significantly correlated with CSAE for students with ACT scores.

H_o3 (a): Neither PPGPA, SQGPA, DGPA, CREDITS or INTERVIEW is significantly correlated with 3S-RCGPA for the entire sample.

(b): Neither PPGPA, SQGPA, DGPA, CREDITS or INTERVIEW is significantly correlated with CSAE for the entire sample.

H_o4 (a): 3S-RCGPA and CSAE means do not differ significantly between GENDER groups.

(b): 3S-RCGPA and CSAE means do not differ significantly between AGE groups.

(c): 3S-RCGPA and CSAE means do not differ significantly between TIME groups.

(d): 3S-RCGPA and CSAE means do not differ significantly among SIZE groups.

(e): 3S-RCGPA and CSAE means do not differ significantly among OFF-CAMPUS groups.

Methods

Seventy-four students from seven consecutive respiratory care classes comprised the sample. The first class entered in 1987 and the last class entered in 1993.

Developing the Model

Twenty students had no ACT scores, so for H_o2, $n = 54$. Three students lacked interview data; therefore, the sample's INTERVIEW mean score was substituted for the missing data, and H_o3, $n = 74$.[3,16]

INTERVIEW scores were produced by respiratory care faculty members. An instrument using a 5-point Likert-type scale guided faculty as they rated the candidates' personality, academic ability, motivation, involvement in outside interests, and maturity. The average of all subscores from all faculty then produced a single INTERVIEW value for each candidate. Faculty were aware of the students' preprofessional academic record during the interview. We believed that the interview was structured enough to provide a valid interval-level measurement.

* See related editorial on page 1038.

Students must earn at least a C in their preprofessional courses to apply to our program. When students earned less than a C and repeated a course, we used *both* the failing grade and the passing grade when calculating SQGPA and PPGPA.

CREDITS was logarithm transformed to satisfy the assumption of normality, yielding TCREDITS. One extreme value was removed (n = 73).

Subjects were placed into groups as shown in Table 1.

Table 1. Groups, Limits, and Sizes of Categorical Variables

Variable	Group	Limits	n
TIME (Years)	1	1991-1993	42
	2	1987-1990	32
SIZE (students)	1	5-8 students in 3 classes	20
	2	12 students in 2 classes	24
	3	14 & 16 students in 2 classes	30
AGE (years)	1	19-20	42
	2	21-37	32
OFF-CAMPUS	Native	0	21
(courses)	Low	≤ 29%	27
	High	≥ 30%	26

Statistical Analysis

Because 3S-RCGPA and CSAE were continuous variables and normally distributed, a multivariate analysis of variance (MANOVA) model was used to simultaneously compare entry-level outcome means for these variables. If the 3S-RCGPA-CSAE correlation proved significant, we could assume that 3S-RCGPA and CSAE each contributed to the definition of entry-level. Therefore, if H_o1 was rejected, MANOVA would be used to address group differences. If H_o1 were accepted, separate ANOVAs comparing CSAE means were planned for each group. H_o4 required 5 MANOVAs. To preserve Type-I error at the 0.05 level required using an α of 0.01 for individual MANOVAs. For significant MANOVAs, post-hoc comparisons were made using ANOVA with Fischer's Least-Significant-Difference test to compare individual dependent variable group means. All other α values were set at 0.05.

SAS version 6.07 (SAS Institute Inc, Cary NC) was used to analyze the data.

Results

Hypothesis 1

H_o1—3S-RCGPA is not significantly related to CSAE. Table 2 illustrates that 3S-RCGPA and CSAE are significantly, though only moderately ($R^2 = 0.192$) related. The first null hypothesis is rejected in favor of the alternative hypothesis (H_a1)—3S-RCGPA is significantly and moderately related to CSAE. Table 2 also shows that several variables might serve as significant predictors of 3S-RCGPA and CSAE. However, significant intercorrelations among potential independent variables indicated that overlapping variance among predictors may make it impractical to use some of these variables in the same regression model. So, the multiple regressions continued as planned.

Hypothesis 2

H_o2 (a)—Neither ACT, PPGPA, SQGPA, DGPA, TCREDITS, nor INTERVIEW correlate significantly with 3S-RCGPA for the students with ACT scores. The Max R^2 procedure found that PPGPA was the single best predictor of 3S-RCGPA, and, with PPGPA in the model, SQGPA never was inserted given its singularity with PPGPA. The forward stepwise procedure ran to a 5-variable model ($R^2 = 0.644$, $F = 17.38$, $p < 0.0001$) and included, in order of strength: PPGPA ($F = 16.49$, $p = 0.0002$), ACT ($F = 10.95$, $p = 0.0018$), TCREDITS ($F = 2.69$, $p = 0.1077$), DGPA ($F = 0.99$, $p = 0.3252$) and INTERVIEW ($F = 0.25$, $p = 0.6167$). Backward elimination regression confirmed that PPGPA and ACT were contributing most of the predictive power in this model. With PPGPA, ACT and TCREDITS as predictors, 3S-RCGPA model R^2 was 0.635. When TCREDITS was eliminated, R^2 fell slightly, but not significantly, to 0.608 ($F = 39.49$, $p < 0.0001$) for the model that had PPGPA (partial $R^2 = 0.528$,

Table 2. Correlation Matrix for Continuous Data (n = 73)

	PPGPA*	SQGPA	DGPA	INTERVIEW	ACT	3S-RCGPA	CSAE	TCREDITS
PPGPA	1.000	0.920†	0.328‡	0.675†	0.331‡	0.655†	0.316‡	–0.146
SQGPA		1.000	0.672†	0.629†	0.298‡	0.658†	0.287‡	–0.111
DGPA			1.000	0.241‡	0.074	0.347‡	0.095	0.008
INTERVIEW				1.000	0.256	0.462†	0.032‡	–0.055
ACT (n = 54)					1.000	0.506†	0.455‡	–0.069
3S-RCGPA						1.000	0.438†	–0.053
CSAE							1.000	0.018
TCREDITS								1.000

*PPGPA, preprofessional grade point average; SQGPA, science and quantitative GPA; DGPA = PPGPA–SQGPA; INTERVIEW, interview score; ACT, American College Test; CSAE, certified respiratory therapy technician self-assessment examination; TCREDITS, logarithm transformed credits (total preprofessional college credits).
† $p < 0.001$.
‡ $p < 0.05$.

$F = 58.21$, $p < 0.0001$) and ACT (partial $R^2 = 0.080$, $F = 10.33$, $p = 0.0023$) as multiple correlates with 3S-RCGPA. H_o2 (a) was rejected in favor of the alternative hypothesis (H_a): H_a2 (a)—For the subgroup with ACT scores, PPGPA and ACT are significant multiple correlates with 3S-RCGPA. Therefore, 3S-RCGPA can be reliably predicted for those with ACT scores using the following regression equation:

$$\text{3S-RCGPA} = \text{PPGPA}(0.721) + \text{ACT}(0.043) + 0.322.$$

H_o2 (b)—Neither ACT, PPGPA, SQGPA, DGPA, TCREDITS, nor INTERVIEW correlate significantly with CSAE for the students with ACT scores. The Max R^2 procedure again left out SQGPA and extended to 5 variables. The model explained 31% of CSAE variance. This time ACT was the strongest predictor. Backward elimination showed DGPA (partial $R^2 = 0.003$, $F = 0.22$, $p = 0.6396$) and INTERVIEW (partial $R^2 = 0.004$, $F = 0.28$, $p = 0.5989$) as clearly extraneous or redundant variables because removing them did not cause the model R^2 to drop at all. When TCREDITS (partial $R^2 = 0.023$, $F = 1.64$, $p = 0.2061$) was removed, the model R^2 fell slightly to 0.287, but the change was found not significant by the backward elimination procedure. The CSAE model R^2 was 0.287 ($F = 10.29$, $p = 0.0002$) when ACT (partial $R^2 = 0.208$, $F = 13.61$, $p = 0.0005$) and PPGPA (partial $R^2 = 0.080$, $F = 5.72$, $p = 0.0205$) were included. Therefore, we rejected H_o2 (b) in favor of H_a2 (b) — For the subgroup with ACT scores, ACT and PPGPA were significant multiple correlates with CSAE. CSAE could then be predicted for those with ACT scores using the following regression equation:

$$\text{CSAE} = \text{ACT}(0.693) + \text{PPGPA}(4.605) + 48.028.$$

Hypothesis 3

H_o3 (a)—Neither PPGPA, SQGPA, DGPA, TCREDITS, nor INTERVIEW correlate significantly with 3S-RCGPA for the entire sample. Running Max R^2 without ACT to predict 3S-RCGPA revealed that SQGPA was the first variable to enter the model. Evidently, there was enough independent variance between SQGPA and PPGPA for PPGPA to enter next. However, having PPGPA and SQGPA in the model weakened the power of either variable to predict 3S-RCGPA variance as both demonstrated insignificant ($p > 0.10$) explanations of 3S-RCGPA variance at Step 2. Proceeding to the backward elimination regression, we withheld PPGPA to preserve SQGPA explanatory power. With SQGPA, DGPA, INTERVIEW, and TCREDITS as multiple correlates, the model R^2 was 0.453 ($F = 14.09$, $p < 0.0001$). After removing INTERVIEW (partial $R^2 = 0.0002$), TCREDITS (partial $R^2 = 0.004$), and DGPA (partial $R^2 = 0.013$), 3S-RCGPA model R^2 value was not significantly lower (0.436) and reflected the partial R^2 for SQGPA as the sole variable left in the model. With only SQGPA as a predictor of 3S-RCGPA, F value was 54.88 ($p < 0.0001$). H_o3 (a) was rejected in favor of H_a3 (a)—For the entire sample, SQGPA is a significant correlate with 3S-RCGPA. Predicting 3S-RCGPA with no ACT score available can be accomplished with the following regression equation:

$$\text{3S-RCGPA} = \text{SQGPA}(0.623) + 1.659.$$

Because SQGPA and PPGPA were such similar variables, we wanted to compare 3S-RCGPA prediction for both variables. If PPGPA and SQGPA explained similar degrees of 3S-RCGPA variation, then they could be considered truly interchangeable, which would allow us more flexibility in choosing predictor variables and potentially simplify the student selection process. The R^2 was 0.428 ($F = 53.04$, $p < 0.0001$) for the 3S-RCGPA multiple regression equation using PPGPA as a predictor. INTERVIEW (partial $R^2 = 0.0002$), TCREDITS (partial $R^2 = 0.004$), and DGPA (partial $R^2 = 0.022$) again fell away as nonsignificant multiple correlates. Hypothesis H_o3 (a´) was rejected for H_a3 (a´)—For the entire sample, PPGPA is a significant correlate with 3S-RCGPA.

Predicting 3S-RCGPA for those without ACT scores can be accomplished using PPGPA almost as accurately as with SQGPA using

$$\text{3S-RCGPA} = \text{PPGPA}(0.777) + 1.089.$$

H_o3 (b)—Neither PPGPA, SQGPA, DGPA, TCREDITS, nor INTERVIEW correlate significantly with CSAE for the entire sample. Running Max R^2 without ACT to predict CSAE showed that PPGPA (partial $R^2 = 0.100$) explained the majority of CSAE variance. The procedure continued to a 3-variable model that included PPGPA, INTERVIEW (partial $R^2 = 0.015$), and TCREDITS (partial $R^2 = 0.002$). Improvement in CSAE model R^2 stopped at 0.113. Backward elimination regression found that only PPGPA explained a significant degree of CSAE variance ($R^2 = 0.100$, $F = 7.71$, $p = 0.007$). H_o3 (b) was rejected and replaced with H_a3 (b)—For the entire sample, PPGPA is a significant correlate with CSAE. Predicting CSAE values for those without ACT scores can be done using

$$\text{CSAE} = \text{PPGPA}(4.610) + 62.847.$$

Hypothesis 4

Because H_o1 was rejected, MANOVA was applied to the remaining prospectively planned hypotheses. 3S-RCGPA and CSAE means do not differ significantly among GENDER [H_o4 (a)], AGE [H_o4 (b)], TIME [H_o4 (c)], or SIZE [H_o4 (d)] groups. These data are given in Table 3.

H_o4 (e)—3S-RCGPA and CSAE means do not differ significantly among OFF-CAMPUS groups. Simultaneously comparing 3S-RCGPA and CSAE means among OFF-CAMPUS groups produced an F value of 3.76 (df 2,71; $p = 0.0062$) by MANOVA, so H_o4 (e) was rejected in favor of H_a4 (e). We proceeded to compare 3S-RCGPA and CSAE means among OFF-CAMPUS

Table 3. Summary of Analysis of Variance for Categorical Variables Contributing to the Multivariate Analysis of Variance.

Hypothesis	Variable	Groups	n	Mean (SD) 3S-RCGPA*	Mean (SD) CSAE	p
4 (a)	GENDER	Women	51	3.15 (0.54)	74.6 (7.2)	
		Men	23	3.35 (0.51)	77.4 (5.0)	0.18
4 (b)	AGE (range, years)	1 (19-20)	42	3.26 (0.51)	75.5 (6.5)	0.75
		2 (21-37)	32	3.17 (0.57)	75.5 (7.0)	
4 (c)	TIME (year graduated)	1 (1990-1993)	42	3.38 (0.53)	75.9 (7.1)	0.06
		2 (1987-1989)	32	3.10 (0.52)	75.2 (6.4)	
4 (d)	SIZE (students/class)	1 (5-8)	20	3.39 (0.58)	77.1 (6.2)	0.07
		2 (12)	24	3.28 (0.46)	74.0 (7.4)	
		3 (14-16)	30	3.06 (0.53)	75.7 (6.2)	

* 3S-RCGPA, grade-point average from the first 3 semesters of the respiratory care program; CSAE, certified respiratory therapy technician self-assessment examination

groups by ANOVA. Both 3S-RCGPA and CSAE mean comparisons among the 3 off-campus groups revealed significant trends. Table 4 shows that Native students had higher 3S-RCGPA and CSAE means. Because the 95% 3S-RCGPA and CSAE confidence intervals of the Native OFF-CAMPUS group did not overlap the interval ranges of the Low and High OFF-CAMPUS groups, we found that these differences were practically and statistically significant. Therefore, we accepted H_a4 (e)—3S-RCGPA and CSAE means *do* significantly and practically differ among OFF-CAMPUS groups.

Testing a Post-Hoc Hypothesis

Returning to the regression equations for H_o2 and H_o3, we noticed that partial R^2 for PPGPA dropped systematically when the 21 students lacking an ACT score were added to the sample. This raised a post-hoc null hypothesis: H_o4 (f)—3S-RCGPA and CSAE means do not differ between groups of students with and without ACT scores. Addressing these hypotheses required grouping subjects based on whether they had an ACT score to create the independent variable and simultaneously comparing 3S-RCGPA and CSAE means between the ACT groups by MANOVA. Students without an ACT score (n = 20) had 3S-RCGPA and CSAE means [SD] of 3.30 [0.63] and 76.4 [6.6] compared to those students with ACT scores (n = 54) who had means [SD] of 3.19 [0.50] and 75.2 [6.7]. MANOVA produced an F value of 0.407 (df 2,71; p = 0.67), so H_o4 (f) was accepted.

Summary of Accepted Hypotheses

H_a1: 3S-RCGPA is significantly but moderately related to CSAE.

Table 4. Analyses of Variance Comparing 3S-RCGPA* and CSAE Means (SD) among Groups of Students Formed according to the Percent of Classes Taken Off Campus.

Group	n	Lower 95% CI	3S-RCGPA mean (SD)	Upper 95% CI	min	max
Native (0%)	21	3.29	3.51 (0.46)[A]	3.73	2.67	4.00
Low (1-29%)	27	2.84	3.04 (0.51)[B]	3.24	2.16	4.00
High (30-100%)	26	2.96	3.16 (0.54)[B]	3.36	2.09	4.00
Group	n	Lower 95% CI	CSAE mean (SD)	Upper 95% CI	min	max
Native (0%)	21	76.4	79.1 (4.7)[A]	81.9	69	91
Low (1-29%)	27	70.7	73.1 (7.5)[B]	75.5	61	86
High (30-100%)	26	72.6	75.1 (5.9)[B]	77.5	63	86

* 3S-RCGPA, grade-point average from courses taken during the first 3 semesters of the respiratory care program; CSAE, certified respiratory therapy technician self-assessment examination; CI, confidence interval; min, minimum value; max, maximum value.

3S-RCGPA model F = 5.30; df 2,71; p = 0.0072; CSAE model F = 5.54; df 2,71; p = 0.0058. Means with the same letter are not significantly different by Fisher's least-significant-difference test ($p < 0.05$).

H_a2 (a): For the subgroup with ACT scores, PPGPA and ACT are significant multiple correlates with 3S-RCGPA.

H_a2 (b): For the subgroup with ACT scores, ACT and PPGPA are significant multiple correlates with CSAE.

H_a3 (a): For the entire sample, SQGPA is a significant correlate with 3S-RCGPA.

H_a3 (a′): For the entire sample, PPGPA is a significant correlate with 3S-RCGPA.

H_a3 (b): For the entire sample, PPGPA is a significant correlate with CSAE.

H_o4 (a): 3S-RCGPA and CSAE means do not differ significantly between GENDER groups.

H_o4 (b): 3S-RCGPA and CSAE means did not differ significantly among AGE groups.

H_o4 (c): 3S-RCGPA and CSAE means do not differ significantly between TIME groups.

H_o4 (d): 3S-RCGPA and CSAE means did not differ significantly among SIZE groups.

H_a4 (e): 3S-RCGPA and CSAE means do significantly and practically differ among OFF-CAMPUS groups.

H_o4 (f): 3S-RCGPA and CSAE means do not differ between groups of students with and without ACT scores.

Discussion

Op't Holt and Dunlevy[1] used exit *cumulative* GPA as their dependent variable and analyzed preprofessional GPA, GPA from courses in science and mathematics, and interview scores as predictors. These authors defined exit GPA as the students' "...grade point upon (respiratory care) program completion." Therefore, exit GPA was an aggregate of their students' preprofessional- and professional-course grades. Because exit GPA is a composite of preceding semester GPAs, we did not think that exit GPA was the best dependent variable for our study. We found that exit GPA was not independent of some of the potential correlates, PPGPA and SQGPA. In fact, it was inevitable that exit GPA would correlate with its components (semester GPAs, SQGPA, and PPGPA). Also, our emphasis on entry-level outcomes caused us to be more concerned about achievement after the first 3 semesters of respiratory courses; so, when compared to Op't Holt and Dunlevy's[1] study, we used a clearly different dependent variable.

Because the conclusion of the Junior year corresponded with our students' acquiring entry-level skills, we also used CSAE as a dependent variable. Because students were required to pass the CSAE, we believed this to be a particularly appropriate time and measurement against which our selection method could be compared. Support for this approach was offered by evidence that all our students graduated after successfully completing the first 3 semesters of respiratory care courses. Also, this interim point was more closely related, in time, to generation of the variables that we believed held greater potential for finding defensible predictors. Given the evidence emphasizing the importance of measuring Junior year GPA[3,5] to get an early indication of progress, we found more support for using 3S-RCGPA as another entry-level outcome measure.

Besides measuring different outcomes and multiple dependent variables, a second point upon which our approach diverged from that taken by Op't Holt and Dunlevy[1] lay in our modeling goal. Op't Holt and Dunlevy's[1] goal involved predicting who might not succeed to *screen* them out. We too relied on prediction, but our goal was to establish a defensible model for *selecting* students who would have a reasonable chance of success. The distinction may not be apparent initially. McGaghie[6] suggests that selection is not the same as prediction, as is often presumed, and goes on to state that selection involves making a choice based on *preferences* and *values* while prediction (with intent to screen) attempts to *forecast* future achievement. The distinction is subtle, yet important.

Consider that 16 student slots are available in our respiratory care program. Suppose we have 20 applicants, but we cannot be 95% sure that the last 6, with weaker academic records, will not fail as predicted by regression modeling. However, their PPGPA is high enough to remain enrolled in the university. If the goal of our predictive modeling was to screen out poor risks, then even though our class would not be full, we would exclude any candidates whose success was not predicted with 95% confidence. This would leave 2 open slots in our class. Given that only 60% of 3S-RCGPA and 29% of CSAE variation was explained by our predictive models, we found it unreasonable to attribute the entire selection decision to those models. We would select 2 more candidates from the 6 who had lower apparent abilities and fill the class because a full class maximizes opportunity. One might be concerned that indiscriminate class-filling lowers educational standards. However, we believe that professional standards are conveyed and reinforced to students as they move through the program, not when they are at the point of admission. Even though we select students with the expectation that all will graduate, we are unwilling to impose an artificially high admission standard because our prediction model still has a good deal of unexplained variation.

The fact that 3S-RCGPA is significantly related to CSAE (H_a1) suggests that ranking prospective candidates on the basis of a 3S-RCGPA regression is defensible. The fact that there is only a moderate correlation between 3S-RCGPA and CSAE suggests that using both predicted 3S-RCGPA and CSAE to rank candidates is defensible and desirable. We believe that by using both ranks we more completely define entry-level status; so, our selection methods ought to include both measures.

PPGPA and ACT are significant multiple correlates with both 3S-RCGPA [H_a2 (a)] and CSAE [H_a2 (b)] for students with ACT scores. The strongest predictor of GPA in the first 3 semesters of our respiratory care program is another GPA. Similarly, the best predictor of the CSAE score is the score from another test—the ACT. McGaghie[6] has already suggested that these relationships would hold true for this population, and our find-

ings support his assertion. Because we intend to use both entry-level outcome measures to select students, it seems defensible to use both PPGPA and ACT as selection criteria. This decision is further supported when one understands that ACT contributes something additional to 3S-RCGPA prediction and PPGPA contributes to CSAE prediction as shown in the distribution of error in the regression.

SQGPA [H_a3 (a)] and PPGPA [H_a3 (a´)] correlates significantly with 3S-RCGPA for the entire sample; PPGPA also correlates with CSAE [H_a3 (b)] for the entire sample. In the absence of ACT scores, PPGPA is a reliable predictor of both measures of our students' entry-level status. In the absence of an ACT score, there is no practical difference between SQGPA ($R^2 = 0.436$) and PPGPA ($R^2 = 0.428$) when predicting 3S-RCGPA. The high intercorrelation between SQGPA and PPGPA and the fact that the R^2 values for 3S-RCGPA prediction are basically the same with SQGPA and PPGPA as predictors support this conclusion. Therefore, the computation of SQGPA is probably unnecessary; PPGPA is sufficient.

The strength of predictions made without ACT is less than that offered by PPGPA and ACT together, but PPGPA offers the next best alternative, and its use as the sole selection criterion for students without ACT scores is defended by the evidence. This evidence suggests using separate regression equations to rank candidates based on predicted 3S-RCGPA and CSAE depending on whether the student had an ACT score. Because predictive power of 3S-RCGPA and CSAE was weaker without ACT than it was with ACT, we considered whether ACT should be required of all candidates. However, we are unwilling to impose this requirement because using ACT scores earned after some college experience is not a standard practice. The validity of such inferences has not been established. We found no difference in 3S-RCGPA and CSAE between groups of students with and without ACT scores [H_o4 (f)]; therefore, no basis exists for excluding candidates without ACT scores.

Op't Holt and Dunlevy[1] and Tompkins and Harkins[8] failed to find support for interview scores from multivariate models in respiratory care populations. Op't Holt and Dunlevy[1] considered dropping the interview as an entry requirement for their program. Although we failed to find that INTERVIEW added to entry-level outcome prediction, we decided to modify rather than drop the interview procedure after recognizing the strong correlations between interview, PPGPA, and SQGPA. Tompkins and Harkins[8] also found that interview scores had significant Pearson correlations with clinical performance, but then found interview scores shared too much variance with other eventual multiple correlates to be of use as a student-selection criterion. It seems that the interview variable reflected what faculty knew about students' preprofessional academic records. With PPGPA and ACT, interview became redundant. Given that 40% of 3S-RCGPA variance remains unexplained by PPGPA and ACT, we decided to modify our interview format to identify some variation in entry-level outcome that might be explained by nonacademic factors. By withholding academic data from the faculty during the interview and directing their attention to nonacademic areas, we hope to add to what we can reliably predict about entry-level achievement.

The number of preprofessional college credits a student accumulates may offer some additional weak prediction. At least, we are unwilling to rule out the possibility that CREDITS might significantly add to explaining entry-level variance for our population. Therefore, CREDITS deserves a second look as a predictor when we again examine entry-level-outcome predictors. Given that students come with a variety of preprofessional courses, we are comfortable using PPGPA for our first look at entry-level predictors because similar studies also used GPAs and because PPGPA could be derived regardless of the particular mix of courses. However, now that PPGPA is an important predictor in our program selection model, more detailed analysis of preprofessional experiences can be generated by using individual course grades as predictors. Of course, this introduces methodologic complications associated with whether a grade in one biology class is equivalent to the same grade in another class or whether a grade is comparable to one earned at another institution. Further, given that some candidates apply, having taken courses that others have not taken, suggests that we would have to contend with missing data or define a core set of courses that all candidates must have taken, just to be considered for our program. However, by narrowing the scope of predictors we risk missing an important variable. Given these issues, we are satisfied to examine the composite PPGPA for our first look at entry-level prediction.

Retrospectively considering the DGPA concept (PPGPA–SQGPA), we find that a more substantial difference and, thus, a potentially stronger predictor might be found if SQGPA were compared to the GPA students earned in their general-education courses rather than PPGPA. The SQGPA used in our study is part of PPGPA, making the difference between the two GPAs smaller than it might have been using the other method.

3S-RCGPA and CSAE means did not differ significantly between GENDER [H_o4 (a)] or AGE [H_o4 (b)] groups. Our purpose for including these variables in our modeling was to duplicate earlier work. The fact that entry-level outcome does not systematically vary with GENDER and AGE supports omitting these variables from consideration when screening candidates. However our model does not apply to students > 37 years of age—the upper limit of our data.

Women comprised about two thirds of our sample, and roughly three fourths of our students were of traditional college age (19-22 years). This was a baccalaureate-level advanced-practitioner respiratory care program, not a '2 + 2' or technician program. Our sample included four racial minority students over the 7-year period. However, analyzing such a small group as an independent variable was found statistically impractical. Therefore, our sample had minority representatives and may generalize in a limited way to other mixed

populations, but this study cannot extend what is known about the performance of minorities.

3S-RCGPA and CSAE means did not differ significantly between TIME [H_o4 (c)] and SIZE [H_o4 (b)] groups. Among the nonsignificant means comparisons shown in Table 3, TIME as SIZE were close enough to our conservative α that we cannot rule out that a similar study, using a larger sample might reject these null hypotheses. The relationship between the passing of time and class size that we noted while planning this study was apparent during the analysis because the two variables reacted similarly with 3S-RCGPA and CSAE. A bivariate plot of TIME and SIZE exposed an inverse, nonlinear relationship, and we concluded that the TIME variable was primarily reflecting the variance in SIZE. This suggests that class size should be considered in future analyses of entry-level outcomes because we are unwilling to rule out the existence of SIZE effects in the population.

The OFF-CAMPUS variable did explain systematic variation on both entry-level outcomes suggesting that those completing all preprofessional courses on-campus—native students—tended to perform better on 3S-RCGPA and CSAE [H_o4 (e)]. This phenomenon has also been reported by Parker[13] who found that native students tended to do better in medical school. However, we know little about the factors that might explain why native students have better success in medical and professional schools. We suggest that future research on native effects consider several factors. Kegel-Flom[12] found that institutional competitiveness was an important predictive factor for some students, suggesting that other institutions where our students had previously been enrolled may not have been as academically competitive or rigorous. Some students take off-campus courses because of convenience. For example, while home for the summer some take courses offered at the local state or community college. We have observed that some students want to take courses off-campus when they perceive the on-campus equivalent to be more demanding. It could be that students who take some or all of their courses off-campus may have systematically different cognitive abilities or are differentially motivated compared to students who take all on-campus courses. Off-campus students may be less certain of their career goals. Whether the native effect introduces an institutional factor or student factor is impossible to surmise, but we do know that the native effect reflects something about our students' achievement of entry-level status.

While comparing means among GENDER, AGE, TIME, SIZE, ACT, and OFF-CAMPUS groups, we included standard deviations for two reasons. First, this allowed us to better assess whether we had met the homogeneity of variance assumption and permit later inclusion in a meta-analysis. Tabachnick and Fidell[16] have suggested that when faced with unequal group sizes, meeting the homogeneity of variance assumption is an important matter. Particularly when smaller groups display larger degrees of variance, F tests are liberalized to the point where it may be too easy to reject the null hypothesis.[16] The ACT, AGE, and SIZE groups displayed a mild liberalizing trend for 3S-RCGPA, while AGE and SIZE also displayed a mild liberalizing trend for CSAE. However, the null hypotheses were accepted for each of these variables. Therefore, we were satisfied that these analyses were not adversely affected by liberalizing the F test. In fact we assert that even though rejecting the null hypotheses *may* have been increasingly probable, the null hypotheses were accepted anyway.

Where it really mattered, the smallest (Native) OFF-CAMPUS group demonstrated the smallest 3S-RCGPA and CSAE variances. The Low and High OFF-CAMPUS groups were similar in size to one another and displayed nearly equivalent 3S-RCGPA variances. However, CSAE variance for the same comparison was greatly different. We again turned to Tabachnick and Fidell[16] to help us analyze the robustness of the ANOVAs for 3S-RCGPA and CSAE means among OFF-CAMPUS groups. "If there are at least 20 degrees of freedom for error in a univariate ANOVA, the F test is said to be robust to violations of normality...the larger the sample size the less effect nonnormality of variables is likely to have on your conclusions. With grouped data with large samples, transformation of variables is less imperative."[16] Our ANOVAs on OFF-CAMPUS groups had 71 error degrees of freedom, far above what is considered minimal. We took the necessary screening steps to assure that 3S-RCGPA and CSAE were normally distributed. Other variables that failed to meet assumptions were either transformed or downgraded. Therefore, we are satisfied that the assumptions of our planned analyses have been met well enough that the probability of Type-I error is probably not inflated; so, we confidently draw conclusions from the OFF-CAMPUS mean comparisons.

3S-RCGPA and CSAE means do not differ among those with and without ACT scores [H_o4 (f)]. When available, ACT scores added to the prediction of entry-level measures, but having an ACT score does not differentiate between entry-level performances. Whether a candidate has an ACT score will not be considered for future student selection decisions.

The way we intend to use our regression models is fundamentally different from the way Op't Holt and Dunlevy[1] used theirs. While they compared each candidate against their model, we intend to *rank* candidates based on our 3S-RCGPA and CSAE prediction models and then compare candidates to see whom we should select. This is the elemental difference between modeling to screen and modeling to select. With these two studies, respiratory care educators now have two distinct models to use when conducting similar studies of their programs.

Our results are limited to students applying to our respiratory care program. We suspect that technician and therapist populations differ, in part, because of differing admission requirements and market factors. Therefore, we do not recommend that other programs utilize our findings directly in selecting students. Rather, we recommend that others

wanting to defend how they select students conduct their own studies using either this study as a selection model or Op't Holt and Dunlevy's[1] study as a screening model to develop a model that will generalize to their particular program and goals. Both models involve prediction. At issue is whether one seeks to screen out poor risks or select those with a reasonable chance to succeed. This is not a scientific issue; it is a philosphical issue.

In Conclusion

Our current selection model favors academic predictors. Therefore, nonacademic achievement constructs may add to our predictive abilities. By modifying our interview, we hope to strengthen our selection process by tapping previously unexplained variation of academic success. If the new interview format proves incapable of supporting student selection, we may consider using one of the standardized measures of aptitude, IQ, personality, or cognitive-learning-style preferences for which our literature review demonstrated support. A student's accumulation of college credit and class size deserve continued examination as predictors; we remain unwilling to rule out that these may hold some predictive power within the population. However, if class sizes remain near maximum, the variance of SIZE will diminish to the point where prediction will likewise shrink from its already weak position. Also, it may be worthwhile to analyze individual course grades that comprise PPGPA. However, by doing so we can only hope to better understand PPGPA. If the fundamentals of PPGPA and ACT prediction remain the same, we can expect to explain no more than 60% of 3S-RCGPA variance with individual course grades because 3S-RCGPA is merely a composite measure and cannot represent more than the sum of its parts.

Selecting our students on the basis of academic ranks is now defended by objective evidence. Because the 3S-RCGPA model explained twice (60%) as much variance as the CSAE model (29%), it is appropriate to assign twice as much weight to predicted 3S-RCGPA rank as compared to predicted CSAE rank when constructing a grand selection rank. We intend to create a separate rank based on the new interview. After a sufficient sample has been collected, we will repeat this analysis looking particularly for increased explanation of 3S-RCGPA and CSAE variance from using the new interview.

The native effect seems a fairly recent discovery and deserves continued attention as a predictor of success in the study of health-professions. This finding also suggests studying several potential independent variables that could increase our understanding of the native effect. We suggest that these areas of study hold the potential for producing better measures of factors that could be used to improve student selection decisions by respiratory-care-education programs.

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Respiratory Care Practitioners as Primary Providers of Neonatal Intubation in a Community Hospital: An Analysis

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BACKGROUND: Respiratory care practitioners (RCPs) serve as the primary providers of neonatal endotracheal intubation (ETI) in our institution. ETIs are performed by registered respiratory therapists who have completed Pediatric Advanced Life Support and Neonatal Advanced Life Support training and have successfully completed 3 intubations under the direct supervision of a senior therapist. The purpose of this study was to (1) ascertain whether RCPs can successfully provide this type of service with acceptable complications rates and (2) survey the economic impact of this practice on patient charges in our hospital. EVALUATION METHODS: An analysis of each intubation event in which an RCP participated was collected and compiled over a 5-month period (9-94 to 2-95). Calculations were made of the success rate and complications. RESULTS: A total of 38 ETIs were performed by the RCPs. Of these, 37 (97.4%) were performed with ≤ 3 attempts; (73.7% with 1 attempt, 15.8% with 2 attempts, and 7.9% with 3 attempts). In only 1 event were more than 3 attempts required. There were no complications observed. CONCLUSION: RCPs can successfully serve as primary providers of neonatal ETI at a Level-II nursery in a community hospital, and this practice may result in a cost reduction. [Respir Care 1995;40(10):1063-1067]

Background

Providing personnel who have the ability to perform safe, timely endotracheal intubation (ETI) is vital in the acute-care hospital. This procedure may be performed by various healthcare providers. Considerable work has been done in ascertaining the ability of properly trained healthcare workers to perform adult ETI both within the hospital[1-3] and outside the hospital.[4-6] Few studies have addressed the competency of nonphysicians in performing neonatal ETI,[7] and we could find few data regarding the success rate of neonatal ETI performed by physicians. In our institution, which is a community-based, nonteaching, 313-bed acute-care hospital with an 18-bed Level-II nursery, respiratory care practitioners (RCP) have been the primary providers of neonatal ETI for approximately 20 years.

All RCPs assigned to the neonatal intensive care unit (NICU) and the delivery room are registered respiratory therapists with Neonatal Advanced Life Support and Pediatric Advanced Life Support certification. The RCP assigned to the NICU is initially supervised by a senior NICU therapist during intubation attempts. A trainee who has successfully performed 3 ETIs without complications is allowed to attempt the procedure unsupervised. The training and clinical performance of the RCPs is closely monitored by the two neonatologists on staff at our institution.

In the current health-care environment, it is imperative that professionals look closely at their scope of practice and identify areas of expertise. Because of our considerable experience with ETI and the apparent lack of information on this subject, we believe it is pertinent to report our experience.

Methods

We evaluated the performance of the RCPs via an analysis of each intubation event in which the RCPs participated during a 5-month period (9-94 to 2-95). The data were obtained from the Neonatal Intubation Form completed by the participating RCP immediately following each event (Fig. 1).

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NEONATAL INTUBATION FORM

Patient Number _____

Weight _____ **lbs/oz** _____ **grams**

Gestational Age (approx) _____ **wks** _____ **term**

Intubation type
- _____ initial
- _____ reintubation due to failure (patient had previously been intubated)
- _____ reintubation due to accidental extubation
- _____ reintubation to increase tube size
- _____ reintubation to replace tube due to age or obstruction
- _____ reintubation for jet-tube placement
- _____ intubation for meconium suctioning
- _____ other (specify)

Intubation attempts
- _____ by RT (number of attempts per therapist)
- _____ # of therapists attempting
- _____ neonatologist
- _____ other (specify)

Intubation—tube size
- _____ 2.5
- _____ 3.0
- _____ 3.5
- _____ 4.0
- _____ other (specify)
- _____ stylet used _____ yes _____ no

How would you classify the intubation
- _____ normal/routine
- _____ somewhat difficult
- _____ difficult

If difficult, what was the cause
- _____ anatomy
- _____ secretions
- _____ patient "fighting"
- _____ patient size
- _____ other (specify)

Indications
- _____ $P_{CO_2} > 60$ with pH < 7.25
- _____ $P_{O_2} < 50$ in > 0.60 F_{IO_2}
- _____ severe retractions
- _____ apnea
- _____ other (specify)

Tolerance of intubation (during attempt)
- _____ bradycardia < 80 beats/min > 30 seconds (requires intubation procedure to be stopped)
- _____ desaturation < 80% > 30 seconds (requires intubation procedure to be stopped)
- _____ other (specify)

Complications
- _____ excessive bleeding
- _____ other

CXR (results)
- _____ good tube placement
- _____ tube too low
- _____ tube too high
- _____ other (specify)

COMMENTS: _____

Fig. 1. All respiratory care practitioners who attempted to intubate were required to complete this form immediately after the procedure.

RCPs are instructed to record any unusual aspects of the procedure and the clinical circumstances surrounding the event. We defined succesful ETI as one that resulted in proper placement with ≤ 3 attempts requiring ≤ 30 s/attempt.[1-3,5,6]

Complications (ie, bleeding, hypoxemia, or bradycardia) were recorded on the Form and tallied. RCPs were instructed to record esophageal intubation as a complication under "other" if it occurred and went unrecognized leading to deterioration in the patient's clinical status. Chest radiograph (CXR) confirmation of ET-tube position in the trachea (1 cm above the carina or at the level of the second thoracic vertebral body) was obtained for all patients for whom the ET tube was indicated for more than a few minute (eg, ETIs performed for meconium suctioning during delivery were not confirmed with CXR). At our institution, all neonatal ET tubes are placed orotracheally.

Results

RCPs participated in 38 ETIs during the study period. The patients ranged in weight from 567 grams to 4,252 grams with a mean weight of 1,659 grams. Successful ETI was documented in 37 ETIs (94.9%). Frequency distribution for success and number of attempts is shown in Figure 2. CXR confirmed proper placement of the ET tube in all cases (76%) of prolonged application.

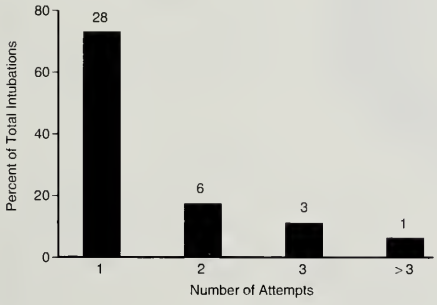

Fig. 2. The distribution of intubation attempts as a percent of the total. Most were accomplished successfully with only 1 attempt.

No clinically important complications were observed.

Approximately 85% of the ETIs were described as "normal/routine," and 15% were described as "somewhat difficult" or "difficult." The latter was due to secretions and/or infant agitation. It is interesting to note that the intubations the RCPs classified as difficult were all in the very small (birthweight ≤ 1,000 g) and in large (birthweight ≥ 3,000 g) infants. However, birthweight-related differential success is not apparent from the data (Table 1).

The indication for intubation was also recorded; these data are given in Table 2.

Table 1. Number of Endotracheal Intubation Attempts, by Categorized Birthweight Group

Weight (gm)	Attempt(s) 1	2	3	>3
<1,000	18	4		
1,001-1,499	1	1	1	
1,500-1,999	2			
2,000-2,999	1		2	
>3,000	6	1		1

Table 2. Reason for Intubation

Initial intubation	41.0%
Reintubation due to AE*	30.8%
Reintubation because patient needed larger ETT†	10.2%
Reintubation to replace ETT due to age or possible obstruction	7.8%
Reintubation due to worsening respiratory status following planned extubation	5.1%
Intubation for meconium suctioning	5.1%

*AE = accidental extubation.
†ETT = endotracheal tube.

Discussion

The competency of nonphysicians in performing adult ETI is well documented.[1-6] However, there are few studies involving neonatal ETI. In a survey of 323 hospitals that provide perinatal and neonatal intensive care, Salyer and Chatburn found that in 27% of respondents RCPs performed ETI.[8] Whereas each hospital is unique in terms of the personnel assigned to perform ETI, it is our experience that RCPs can serve as primary providers of neonatal ETI, especially in the acute-care community hospital where house staff are not present.

Recognizing that ETI is a learned psychomotor skill having been described as "putting the tube through the correct hole expeditiously and without trauma,"[4] we had to determine what successful intubation meant prior to the analysis of our data. A review of the literature exposed investigators who describe success as ≤ 3 attempts/laryngoscopist within 20-45 seconds per attempt.[1-3,5,6] We defined success as ≤ 3 attempts lasting ≤ 30 seconds each. We believe that our definition of success is consistent with the current guidelines, although future studies on this topic are needed.

Two questions provide the foundation for determining who performs ETI, Who is the most qualified? and Who is the most available?[4,9,10] The consensus of the medical community is that physicians, particularly anesthesiologists,[10] should perform ETI. However, where neonates are concerned, neonatologists are the most qualified physicians because of their extensive training and experience in performing ETI. It is the second question that causes us to consider nonphysicians, especially RCPs, as primary providers of neonatal ETI. In the nonteaching, acute-care community hospital, physicians may

not be available at all times to provide ETI, unlike the teaching institution where house staff, residents, or fellows are vying for ETI opportunities for the experience or for teaching.

In our institution, RCPs have provided neonatal ETI for 20 years, and their role is now a matter of policy. In addition to provider availability, other factors were involved in establishing this policy. Our NICU provides both air and ground neonatal transport services to several outlying rural community hospitals. The transport team is comprised of an NICU nurse and an RCP. Because many infants require ETI prior to transport, RCPs must have both the training and experience to successfully perform ETI in the field. Expecting practitioners to perform emergency ETI without having obtained the experience in a controlled environment may erode their confidence and induce frustration. Because our RCPs have been performing ETI during transport, they are now expected to perform the procedure in the NICU even when neonatologists are available. Research has shown a definite correlation between ETI success and the experience of the person attempting ETI.[5,9,11,12] This correlation appears to be consistent for the physician and nonphysician.

Because competency is directly related to experience, the community hospital may afford a reduced opportunity for ETI and, therefore, reduce skills retention, when compared to the large teaching hospital. To allow each practitioner to attain and retain an adequate level of skill in such an environment, a small group of trained and available personnel may prove to be a valuable resource in providing a competent ETI service. Our experience shows that RCPs, when allowed to perform neonatal ETI on a routine basis, are capable of performing the procedure successfully and without major complications.

In our institution one of the more effective methods of providing ETI experience is to have the RCP present at the delivery of every infant suspected of having meconium staining. The RCP is responsible for visualizing the vocal cords and suctioning the trachea if needed.[13] Most RCPs begin to gain the necessary experience and confidence by performing this protocol routinely.

Our analysis exposed 2 topics of concern. First, even though our incidence of accidental extubations (Table 2) is consistent with that in other published reports,[14,15] we have identified the need for better methods of securing the ET tube. Second, some RCPs prefer to use a guide or stylet to ensure tracheal placement even though the literature clearly reveals the potential for complications related to this practice.[16] Although we did not identify any complication that could be directly attributed to the use of stylets, we maintain that extreme caution must be exercised when they are used.

In addition to our analysis of RCPs' level of competency, we investigated what impact this policy has on patient charges at our institution. Because RCPs have served as primary providers of neonatal airway management, they are asked to attend all cesarean-section and high-risk deliveries relieving the pediatricians of this responsibility. However, neonatologists are also present at high-risk deliveries. A substantial number of Level-II nurseries are staffed with pediatricians who also have private practices in addition to their NICU responsibilities. These pediatricians may not always be readily available to attend emergency, high-risk deliveries. Even attending scheduled cesarean-section deliveries may strain the already high workload of most pediatricians. During 1994, RCPs attended 609 deliveries. Based on the standard fee for physicians ($125) and the charge for an RCP to attend high-risk deliveries ($26.50), a reduction in billed charges of approximately $60,000/year can be seen. Although we report only a reduction in billed charges, the potential may exist for true cost-savings when ETI is provided by RCPs. RCPs' participation in the delivery room has been well received by the pediatricians in our institution.

Conclusion

We conclude that properly trained RCPs can competently serve as primary providers of neonatal ETI in a community hospital with a Level-II nursery, and this practice may reduce the cost of providing ETI. We believe that additional research on this topic is warranted to ensure both quality care and efficient use of valuable resources.

ACKNOWLEDGMENTS

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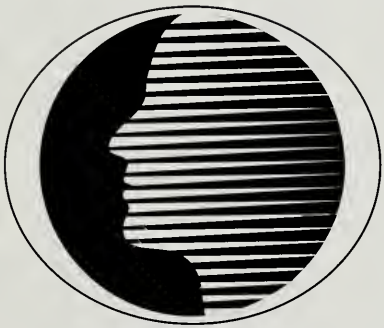

FACE TO FACE WITH CHANGE

AARC 41st Annual Convention and Exhibition
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Remark Office OMR from Principia Products Inc*—optical mark reading software for IBM-compatible computers, $299.

For those of you who are wondering What is an optical mark reader? let me explain. Optical mark readers (OMRs) recognize human-marked areas on forms and convert these data to a form that can be processed (tallied) by a computer. The forms are usually similar to those used with standardized tests, such as aptitude tests or college-entrance exams and require specific markers (ie, #2 lead pencils).

Remark, however, does not require special marking pencils or even special forms; the user can design a form that will tally survey results or grade examinations. Each question or answer field is assigned a specific number of points, and the software records the value in a spreadsheet. Data from this spreadsheet are exportable to several popular spreadsheet and statistical-analysis programs. The only requirement is that the respondent fill a circle (make a clear mark) that can be read by a scanner—at least 30 different scanners are supported by **Remark**.

The documentation—user's manual—supplied with **Remark** is adequate with information that might be required by both the beginning and advanced user. Chapter 1 deals with hardware and installation issues. Chapter 2 is a tutorial—an excellent way to learn the basic features of the software. Chapter 3 is devoted entirely to tips for designing survey/answer forms. Chapters 4, 5, and 6 give advanced and specialized applications instructions, and Chapters 7, 8, and 9 contain the reference guide, instruction for using **Remark** data with other applications, and trouble-shooting and technical support. For users who require handholding (ie, yours truly), the technical-support staff at Principia is cordial and helpful.

The ***CRCE through the Journal*** and Summer Forum CRCE exams were scored using **Remark**—incidentally, we bought our copy! No errors in mark recognition or scoring have been found. **Remark Office OMR** could be a useful tool for educators (no more hand-grading), quality-improvement coordinators (painless data crunching), and human resources personnel with their endless employee satisfaction surveys. Just about anyone who gathers information could make good use of **Remark Office OMR**.

* Available from Principia, 1506 McDaniel Drive, West Chester PA 19380-6682, (800) 858-0860.

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Interdisciplinary Handbook of Adult Lifespan Learning, edited by JD Sinnott, with 42 contributors. Hardcover, 512 pages. Westport, Connecticut: Greenwood Press, 1993. $95.

Interdisciplinary Handbook of Adult Lifespan Learning is a comprehensive review of the theory and research on adult lifespan learning, primarily focusing on the older adult. The Handbook's 28 chapters are unique in that they present concepts about adult lifespan learning in a multidisciplinary format that has been previously unavailable in a single volume. This Handbook serves as a reference to professionals who are interested in adult education and the influence of aging and health on learning. It is an invaluable resource for college professors, graduate students, and researchers. It may also be of interest to therapists, nurses, and physicians who specialize in health promotion or rehabilitation.

The Handbook is divided into 4 sections. The first section examines theories and models for adult lifespan learning, offers unique ways of looking at this particular field, and raises questions that could be examined by researchers. Topics include chaos theory, cooperative biology, systems theory, 'new-science' models, the circle of caring, models for collaboration among teachers and among scientists, the new post-formal cognitive developmental model, and spirituality. Communication technologies as potential enhancements of adult learning are also covered. Because learning styles vary among adults, communication technologies (eg, computers, audio-video recordings, interactive video, and others) can facilitate the learning process.

Section 2 examines the ways adults learn in specific life contexts. The chapters provide information about adult learning in the workplace, health-care facilities, informal groups, the university, psychotherapy, international development projects, and Third World countries. The 3 chapters on empathy and listening skills, learning health-related behaviors, and treatment models for the rehabilitation of memory following brain injury may be the most relevant to physicians, nurses, and respiratory therapists.

The third section is devoted to the subject of learning and aging. Recent research on the effect of training and practice on cognitive abilities in the elderly is critically reviewed. Chapter 25 emphasizes the changes occurring with Alzheimer's disease and suggests interventions for improving outcomes in patients who are in earlier stages of the disease.

In Section 4, the editor outlines 10 factors that make current learning experiences suboptimal for older adults in a rapidly changing world; offers solutions; and proposes that universities restructure or face obsolescence.

This Handbook is an excellent resource for health professionals who are interested in adult education and age-related research. It is relatively easy to read and well organized. The tables are helpful and the bibliography is extensive. Although only a few chapters may be of interest to primary health-care providers, I highly recommend this text as a reference.

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RETROSPECTROSCOPE

How To Succeed in Failing without Really Trying

It's difficult to identify the "who, when, and where" of advances in medicine and surgery because it's a rare advance indeed (such as the use of digitalis by William Withering) that can be clearly related to the astuteness of one person at one time and place. It's a bit easier to identify the "who, when, and where" of some *delays* in progress along a frontier in medical science. To become a "who" who *held up* the advance of science, one must meet certain criteria. These include: (1) The scientist or clinician must be a highly respected "eminent authority" or "geheimrat" in some field; (2) he must have strong convictions; (3) he must not hesitate to utter these forcibly in his writing, lecturing, or both; (4) he must in *this* instance be *wrong*, although he surely doesn't recognize his error; and (5) no one dares to challenge him. Let me give you a few examples of some "whos" who have met these criteria.

Thoracic Surgery

I've already stated my belief that pulmonary surgery was held back for almost 90 years by the failure of surgeons and anesthetists to use simple, well-known, and effective ways of rhythmically ventilating lungs in an open thorax (1). I estimate that 20 to 25 of these 90 years of delay can be attributed to the convictions of an influential authoritarian surgical "geheimrat," Ferdinand Sauerbruch, who, beginning in 1904, performed his operations in an elaborate negative-pressure chamber and ignored the advice (even plea) of Rudolph Matas to use a simple device that inflated and deflated lungs rhythmically instead of producing constant inflation.

This was the same Professor Sauerbruch who later, in 1929-30, had as an intern a young surgeon named Werner Forssmann, who had just published a paper on right heart catheterization in man (for which he was to receive a Nobel Prize 27 years later). Let Forssmann (2) tell of his experiences with Sauerbruch:

> Every time I attempted to talk to the Old Man [about the work on right heart catheterization] I got the feeling that independent thinking was regarded as a dangerous threat. This applied not only to scientific questions but also to problems with patients. An extraordinary inflexibility of thought reigned over the department, a rigid dogma based upon the teachings of Sauerbruch. Any divergent opinions were considered heresy. ... I often wondered why Sauerbruch's surgical department, in itself so excellent, produced so many dull and uninspired doctors. Later I found the answer in a biography of Peter the Great by the eighteenth-century Russian historian M. M. Sherbatov. "How could men remain virile and steadfast when in their youth they had trembled before the rod of their superiors and been praised only for servility?"

And later when Forssmann ventured to express to Sauerbruch the hope that he might qualify for a lectureship, Sauerbruch responded, "You might lecture in a circus about your little tricks, but never in a respectable German university." And when Forssmann protested quietly, Sauerbruch screamed, "Get out! Leave my department immediately." He did, and returned to Eberswalde where he had done his 1929 cardiac catheterization.

Treatment of Essential Hypertension

It is difficult to realize today, when supermarkets sell stethoscopes and manometers for measuring blood pressure and there is a vigorous national mission to reduce high blood pressure by use of antihypertensive drugs, that one hundred years ago physicians thought of high blood pressure only as part of Bright's (kidney) disease. It was not until 1905 that physicians could actually *measure* blood pressure and as late as the 1930s were fearful of lowering a patient's high blood pressure because of the belief that it was compensatory and therefore required to force adequate amounts of blood through the kidneys and probably other vital organs. It was not until the 1950s and 1960s that epidemiologic studies, particularly those at Framingham, Massachusetts, supported by the National Heart Institute, convinced physicians that untreated essential hypertension, even though moderate or mild, shortened life and that high blood pressure demanded vigorous, continuing treatment.

Reprinted with permission of the American Lung Association, from Am Rev Respir Dis 1976;114:629-634.

What held back treatment of essential hypertension? One obvious "what" was that there was no noninvasive, clinical method for measuring systolic and diastolic blood pressure until 1905. That meant that until then it was impossible to learn anything about the effect of very high, high, or moderately high blood pressure on the life span of man. But even when it was apparent that malignant hypertension was a serious, life-threatening disease, physicians doubted the wisdom of lowering high blood pressure. Why? Largely, according to Irvine Page, because of Ludwig Traube, who in 1856 formulated the concept that patients with hypertension *needed* high blood pressure for survival—that it was *essential* to overcome high resistance in narrowed renal arterioles and so maintain excretion of urine (3). He believed it important for the patient's survival that his left ventricle should hypertrophy and maintain a high arterial pressure. Cohnheim, the great German pathologist, promoted Traube's concept.

It was a courageous team (Dr. Rowntree and Dr. Adson and their patient, "a 33 year old, 185 pound man with a blood pressure of 230/130") that showed in 1925 that surgical sympathectomy lowered the patient's blood pressure and he, *mirabile dictu*, instead of dying, actually improved.* A year later, Reid found that lowering blood pressure in hypertensive patients did not impair renal function, and in 1934 Page legitimized deliberate lowering of blood pressure in patients with malignant hypertension when, using the then-new technic of urea clearance, he found well-maintained renal function despite a lower blood pressure. And so 78 years after Traube's dictum was published, the *treatment* of hypertension became *essential*, rather than the *disease*.

Poliomyelitis

In May 1909, Landsteiner and Popper (4) obtained portions of the spinal cord of two patients who had died of poliomyelitis, and injected some of this tissue into the peritoneal cavities of monkeys. One developed paralysis of its lower limbs and died on the sixth day after inoculation; both monkeys, at autopsy, had spinal cord lesions similar to those of patients with poliomyelitis.

Until that time, the cause of the disease was unknown. There had been an epidemic of poliomyelitis along the Atlantic seaboard in 1907 and Simon Flexner, director of the new Rockefeller Institute for Medical Research, began intensive research on the cause of the disease and of its epidemic nature. In 1907 he had attempted to transfer the disease by introducing cerebrospinal fluid from patients into the spinal canal and peritoneal cavity of lower animals; he failed. However, in 1909 he succeeded and reported, "The chart shows unmistakably that by employing the *intracranial* method of inoculation, it is possible to carry the virus of epidemic poliomyelitis successfully through a series of *monkeys*. It is highly probable that the transmission may be carried on indefinitely. ... the outlook for securing a fuller understanding of this disease will be immeasurably improved" (italics added) (5). Indeed, not long thereafter (1911), Flexner issued a press release announcing that his staff had already discovered how to prevent the disease and a cure was just around the corner (6). Yet a safe and effective vaccine did not come for 40 years. Why?

Some workers in the field (6) believe that Flexner, one of the most respected and powerful scientists in America, held back scientific advance in poliomyelitis by insisting that (1) for experimental work, the human disease could be transferred only to monkeys, (2) poliovirus could grow only in nerve tissue, especially in the brain, and (3) the portal of entry of poliovirus was invariably the nasopharynx and that the virus traveled in or along nasopharyngeal nerves to reach the brain. Insistence on point (1) severely limited research on poliomyelitis to well-endowed institutions because monkeys were expensive and there was no National Institutes of Health to pay for them; insistence on point (2) made it difficult to grow poliovirus in quantities needed to produce vaccines; insistence on point (3) precluded work on an oral vaccine of either killed or attenuated poliovirus. As pointed out by Professor Gard in presenting the Nobel Prize for 1954 (7), "Of all tissues, nerve tissue is the most specialized, the most exacting and consequently the most difficult to cultivate. As there seemed to be no alternative to the use of human brain tissue, the general resignation is easily understood."

In the late 1930s and throughout the 1940s, dogma began to crumble. Armstrong showed that polio could be produced experimentally in the cotton rat; Trask, Vignec, and Paul found poliovirus in the stools of polio patients; Burnet and Jackson showed that the virus entered the body of cynomolgus monkeys after *oral* administration; Sabin, and Howe and Bodian, established the gastrointestinal tract as a portal of entry; and Horstmann found poliovirus in circulating *blood* after giving the virus *orally* to monkeys. Finally, Enders, Weller, and Robbins showed in 1949 that poliovirus could indeed be grown in non-neural tissue; in the same year Bodian, Morgan, and Howe learned that only three (and not fourteen) basic immunologic types of poliovirus were needed for immunization. A safe and effective polio vaccine was *then* right around the corner—even an oral vaccine.

Penicillin

On first thought, it seems unfair, in the case of penicillin, even to consider that one or more scientists held back the advance of medical science, since Fleming published his laboratory discovery in 1929 and Chain, Florey, and associates described the remarkable chemotherapeutic effects of penicillin in experimentally infected mice in 1940 and in therapeutic trials in patients a year later. In 1945, all three won the

* I go against established surgical custom by applying the adjective "courageous" to the *patient* as well as to his physicians.

Nobel Prize in Physiology or Medicine. Yet Fleming, in his 1929 paper (8), was curiously unenthusiastic about his work. He did say that penicillin "appears to have some advantages over the well-known chemical *antiseptics* ... a more powerful inhibitory agent than is carbolic acid and it can be applied to an infected *surface* undiluted, as it is non-irritant and non-toxic" (italics added) and "penicillin is certainly useful to the bacteriologist for its power of inhibiting unwanted microbes in bacterial cultures." And it is baffling that although he found that "penicillin is non-toxic to animals in enormous doses ... it does not interfere with leucocyte function to a greater degree than does ordinary broth," he never infected a mouse with penicillin-sensitive micro-organisms to determine whether his nontoxic penicillin, administered systemically, could save the life of the mouse—an experiment easy to do and one that would have required no more than a few hours of his time.

Why? Ernst Chain, co-winner of this Nobel Prize, in 1971 commented in retrospect on Fleming's 1929 work (9):

> I have mentioned that Fleming had injected 0.5 ml of the penicillin-containing culture fluid into mice without any toxic effects. His culture fluid must have contained at least 1-2 units of penicillin per millilitre. It has always amazed me that Fleming did not carry out exactly the same experiment on mice infected with streptococci. No chemical knowledge was required for such an experiment. Had he done this, he would certainly have got *some* chemotherapeutic effect though, maybe, not so striking as the one which we obtained with the more purified preparation. It would have been impressive enough, however, to stimulate chemists into action to get the active principle in a purified form, which actually was not a very difficult operation, and in this they would undoubtedly have succeeded with the result that humanity would have had penicillin at its disposal ten years earlier than it did. The reason why Fleming did not even attempt to carry out this simple experiment, is, in my opinion, that the whole atmosphere in the Institute where he worked, the Inoculation Department of St. Mary's Hospital, was not conducive to this approach; it was, in fact, positively unsympathetic to experiments of this kind. The Director and Head of the Inoculation Department was Sir Almroth Wright, who believed that antibacterial therapy could only be based on immunological techniques, and any attempt to use chemicals was doomed to failure, as all the available experience had shown that they would be more harmful to the host than to the invading bacteria. "Stimulate the phagocytes" was his motto and dogma (he was the model for the doctor [Sir Colenso Ridgeon] in George Bernard Shaw's play *The Doctor's Dilemma*), and he would not readily admit any other view. Fleming was his pupil and junior collaborator, and became himself a strong advocate of immunotherapy and was openly sceptical about the potentialities of chemotherapy. ... it was, after all, six years before the discovery of prontosil and the sulphonamides. [However, it was some years *after* Ehrlich's synthesis of "606" (Salvarsan or arsphenamine), effective against spirochetes without killing their human host, and *after* the successful use of "Bayer 205" (suramin), which killed trypanosomes, again leaving the host alive.]

Despite Leonard Colebrook's defense of Almroth Wright (10), Wright does emerge as "the villain of the piece" (to use Hare's expression [11]). Sir Almroth Wright was an eminent and outspoken experimental pathologist at St. Mary's Hospital who passionately believed that bacterial infections could be conquered only by stimulating the body's natural defense mechanisms and that chemotherapy potent enough to be toxic to bacteria in the host must also be toxic to the host. Wright *almost* used citrate as an anticoagulant for indirect blood transfusions in 1894 but didn't. He was *almost* the first to vaccinate man against typhoid fever, but he was second. His laboratory was *almost* the first to discover the first chemotherapeutic agent against bacteria (6 to 7 years before sulfanilamide) but he wasn't interested in penicillin. Although knighted Sir Almroth Wright, some preferred to call him "Sir Almost Right." In fairness to Wright, Ernst Chain was sure that Wright did not *prevent* Fleming from carrying out chemotherapeutic experiments at St. Mary's. As Chain put it (9):

> However, despite the generally unsympathetic attitude to the possibilities of antibacterial chemotherapy which prevailed in the twenties at the Inoculation Department of St. Mary's Hospital, no one in that Department, and least of all Almroth Wright, would have prevented Fleming from carrying out the simple experiment of injecting the crude penicillin-containing culture medium into a mouse infected with a penicillin-sensitive bacterium if he had wanted to. He did not perform it because he did not think that it was worthwhile trying. I mention this aspect of the history of penicillin discovery as a good example of how preconceived ideas in science can stifle imagination and impede progress; there exist many others of the same type. It is always dangerous when any generally accepted theories or any kind of central dogmas are taken too seriously.

Sir Henry Dale, in his obituary on Fleming, said (12):

> Neither the time when the discovery was made, nor, perhaps, the scientific atmosphere of the laboratory in which he worked, was propitious to such further enterprise as its development would have needed. Repeated failure had caused opinion then to harden, almost into a settled conviction, against the possibility of a successful chemotherapy of the common bacte-

rial infections. Sir Almroth Wright himself had no belief in such a possibility.

Discovery of Oxygen

It's hard to believe that before 1776, there was neither an American Declaration of Independence nor oxygen. Mayow almost discovered oxygen in 1674. He demonstrated that only *part* of air was necessary for life and that part was removed both by respiration and by fire (combustion). This part he called "nitro-aerial spirits." He enclosed an animal and a lighted lamp in a vessel (fortunately, over water that absorbed CO_2) so arranged that air could not enter. The lamp died first (because, as Mayow pointed out, it exhausted the particles immediately around the flame); the mouse died a little later (later, because its breathing brought in particles from a distance). He stated that gills of fish function as lungs and fish survive in water only because it contains nitro-aerial spirits. (He observed that fish cannot live in boiled water since boiling removes the vital substance.) However, he did not realize that the vital substance was a gas that could be isolated.

No one followed up on Mayow's work. Instead, along came Georg Ernst Stahl, physician to the King of Prussia from 1716 to 1734, and his "upside-down" phlogiston theory of combustion. It's hard to explain this "almost-right" theory in a paragraph but it's something like this: All combustible materials contain something that, on heating, is transformed into fire; this "something," since it becomes fire, he named "phlogiston." Combustible materials consisted of a calx or ash combined with phlogiston (which escaped during burning, leaving the ash behind). Fire died out in closed spaces because when air became saturated with phlogiston, no more could leave the combustible material. There was a serious problem with the phlogiston theory: metals when heated gained weight; they then lost weight when converted by charcoal back to metal. Stahl explained away this matter of weight *gain* (when phlogiston was supposed to *leave*) by attributing negative weight to phlogiston (giving it a tendency to float upward).

The discovery of oxygen came 100 years after Mayow's observations. On August 1, 1774, Joseph Priestley, using a 12-inch "burning glass" facing the summer sun, heated mercuric oxide and so released a gas. The chemical equation, as we know it, was:

$$2\,Hg + O_2\,(air) \xrightarrow{+\,heat} 2\,HgO$$

$$2\,HgO \xrightarrow{+\,intense\ heat} 2\,Hg + O_2$$

This he reported to the Royal Society in March 1775. On March 8, 1775, he exposed a mouse to gas he had released from mercuric oxide and found the gas "was much better than common air." Priestley was the first man to breathe O_2, the first to note the beauty and vivacity of a flame in O_2, the first to suggest the use of O_2 and flame to melt platinum and to suggest the use of O_2 in exploding gun powder.

But he didn't really know that he discovered oxygen; he insisted to his death that he discovered "dephlogisticated air." Scheele, who independently discovered oxygen (probably in 1773, although he did not publish until 1777), was also an ardent phlogistonist and also completely entangled in Stahl's theory. And so the discovery of the real significance of oxygen was delayed until 1776 when Lavoisier, completely free of previous dogma, realized its chemical nature and its role in combustion, named it oxygen, initiated the "Chemical Revolution" and ended the phlogiston era.

I'm fascinated by Priestley's own comments on his discovery of "dephlogisticated air." He said (13):

> When the decisive facts did at length obtrude themselves upon my notice, it was very slowly, and with great hesitation, that I yielded to the evidence of my senses. And yet, when I reconsider the matter, and compare my last discoveries relating to the constitution of the atmosphere with the first, I see the closest and the easiest connexion in the world between them, so as to wonder that I should not have been led immediately from the one to the other. That this was not the case, I attribute to the force of prejudice, which, unknown to ourselves, biasses not only our *judgments*, properly so called, but even the perceptions of our senses: for we may take a maxim so strongly for granted, that the plainest evidence of sense will not intirely [sic] change, and often hardly modify our persuasions; and the more ingenious a man is, the more effectually he is entangled in his errors; his ingenuity only helping him to deceive himself, by evading the force of truth.

Here is Priestly, himself hopelessly entangled in an incorrect theory—the phlogiston concept—warning others to stick to the evidence and not give in to their prejudices! Claude Bernard, 100 years later, wrote, "It is the things we *do* know that are the great hindrance to our learning the things that we do *not*.

Cardiac Surgery

Aristotle (ca. 350 B.C.) wrote, "The heart alone of all viscera cannot withstand injury." I suspect that Aristotle's views prevailed until the nineteenth century, because even after the discovery of ether and nitrous oxide and the incursion of surgeons into many organs, none touched the heart. As late as 1883, Billroth, Europe's greatest surgeon, still respected Aristotle when he stated: "A surgeon who tries to suture the heart deserves to lose the esteem of his colleagues" (14). No one challenged Billroth until 1897 when Ludwig Rehn sutured a knife wound in a man's heart and the patient survived. A few years later, a surgeon in Alabama again challenged Bill-

roth and sewed up a stab wound in the heart of a 13-year-old boy; the surgeon's name was Dr. Luther L. Hill, who having studied abroad under Lord Lister, quite naturally named his son Lister Hill (later the U.S. Senate's staunchest supporter of the National Institutes of Health, including the National Heart Institute).

Mackenzie, England's great cardiologist, gets the credit for holding back surgical repair of damaged heart valves because of his strong conviction that one need not worry about the state of the valves as long as the heart muscle is healthy. In 1902 Brunton suggested slitting open fused mitral valve leaflets, and in 1925 Souttar, in London, actually performed an operation on the mitral valve. But after Souttar successfully dilated the stenotic valve by pushing his finger through the orifice, he never did a second operation. Why? Souttar wrote, "It was an article of faith with physicians that the valves were of no importance and that the only thing that mattered was the condition of the heart muscle. In that atmosphere I was unable to obtain another case in spite of this one complete success." Such was Mackenzie's influence in the field of cardiology! John McMichael recalls (15):

> I was present at a discussion meeting of the American Heart Association in 1948 on the rival mitral valvotomies of Harken and Bailey. Dr. Sam Levine recounted how he had written to James Mackenzie to tell him about Elliot Cutler's first effort to open up a stenosed mitral valve in 1923: he read from a letter from Mackenzie: "Dear Sam, What a foolish thing to try to do. Have you forgotten that the myocardium is all-important?"

Measurement of Cardiac Output in Man

Arthur Grollman, the great authority on measurement of cardiac output, held back for a decade the use of indicator dilution technics and the direct Fick method because of supreme confidence in his own acetylene method. In his book *The Cardiac Output of Man in Health and Disease*, Grollman stated unequivocally (16): "Because of its obvious superiority, this gas has displaced other foreign gases for determining the cardiac output. ... The only criticism that can be levelled against acetylene as a gas for determining cardiac output is its taste. ... on repeated use, this initial distaste ... gives way to one of pleasure."

He then demolished the dye dilution technic by pronouncing: "Its underlying assumptions are so complex as to render the results quite questionable. ... The required arterial punctures and the injection of a foreign substance into the blood stream would in themselves render the injection method undesirable and it is unlikely, therefore, that it will find any wide application to cardiac output studies." When cardiologists began to catheterize the right heart of man, they soon got around to measuring cardiac output by both the direct Fick method and the acetylene method; the latter, found to give values far too low, went to its grave.

Concluding Remarks

In my opening paragraph, I gave my formula for "How to succeed in failing without really trying." Fortunately, all five components must be in the recipe or it won't work. It's going to be very hard to eliminate the first four components from our biomedical research family. The hope for the future lies in eliminating the last of the five.

JULIUS H. COMROE, JR.

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75 Years Ago in Texas Medicine

February 1920
A Case of Foreign Body in the Lung

By Sam N Key
Austin, Texas

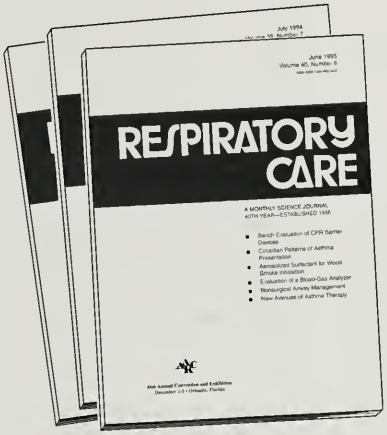
The following case is reported, not to present anything new in bronchoscopy, but to demonstrate the necessity of making an x-ray examination of every person who swallows a foreign body. A.B., a twelve year old girl, while swinging, suddenly swallowed a pin which she was holding in her mouth. She reported this to her mother, but as she presented no symptoms, no cough or sense of discomfort, the incident was not viewed with much alarm.

It is characteristic of small foreign bodies, even though they pass into the lower air passages, that unusually few, if any, symptoms develop for a variable period of weeks or sometimes months. This is responsible for many delayed diagnoses in these cases.

Fortunately, the patient came under the observation of a competent Roentgenologist. An x-ray examination showed the pin in the posterior branch of the right inferior lobe bronchus.

Eight hours after the accident the patient was on the operating table, and under ether-oil colonic anaesthesia, the pin was removed by oral bronchoscopy. Even in this short time, considerable traction was necessary to remove the pin, as the edematous wall of the bronchus firmly held the head of the pin. What would have been a difficult operation was made relatively easy by the early diagnosis.

Texas State Journal of Medicine, 1920;15(10):371. Reprinted with permission.



CRCE through the Journal–1995

Answer Key

For your information, the correct answers to the 50 questions for *CRCE through the Journal*, which appeared in the August 1995 issue of RESPIRATORY CARE, are given below. No scores will be available from the AARC until 1995 transcripts are released in early 1996. Deadline for submission of answer sheets for CRCE credit was September 30, 1995.

1. C	11. D	21. A	31. E	41. A
2. C	12. A	22. D	32. A	42. E
3. A	13. A	23. D	33. B	43. A
4. D	14. C	24. C	34. D	44. B
5. E	15. D	25. B	35. C	45. D
6. E	16. A	26. A	36. D	46. C
7. B	17. E	27. E	37. A	47. D
8. C	18. E	28. B	38. E	48. B
9. B	19. E	29. C	39. B	49. E
10. A	20. C	30. D	40. C	50. A

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Comments on Closed-System Suction Catheters

We read with interest the article by Milisch and his colleagues[1] on the unexpected and unusual complication encountered while using a closed-system directional-tip suction catheter (CSSC). Mr Milisch's group is to be commended for quick clinical assessment and proper treatment of the complication they reported. Although the benefit of the CSSC was identified as an asset in terms of helping to remove the trapped catheter, we are concerned whether the CSSC was in fact the cause of the event—ie, could this have occurred in a standard, open-suction system?

Suctioning is an invasive procedure that is not without complications. Hypoxemia, infection, tissue trauma, cardiac dysrhythmia, and atelectasis have been associated with mechanical aspiration of the lung.[2,3] More recent reports have implicated the CSSC in previously unreported complications associated with suctioning the artificial airway.[4-6] Questions have been raised about the use of the CSSC which, to our knowledge, remain unresolved today.[7-9]

We suggest that, by design, the CSSC in combination with the ventilator settings, the properly sized suction catheter, and the patient's cough while being suctioned within a closed system contributed to the unprecedented exiting of the catheter through the Murphy eye.

A properly sized suction catheter utilized in a closed-airway system with mechanical ventilation increases peak airway pressures, retards passive exhalation, and may even cause intrinsic PEEP.[4] A patient who must cough during the suctioning procedure will exacerbate these adverse effects and complications of the procedure. The increased pressure created by the cough within the closed system, the reflex inspiration following the cough, and the repeat cough following the deep breath, can predispose the patient to the complications associated with positive pressure ventilation, unnecessarily. The higher peak airway pressures exerted during the cough within the closed system may have facilitated the exit of the suction catheter through the Murphy eye of the endotracheal tube.

We caution practitioners against the universal use or casual acceptance of CSSC systems. The current use of the latest ventilatory support modalities, inclusive of pressure-controlled ventilation, pressure-controlled ventilation with inverse I-E ratios, and the use of PEEP mandate that clinicians be thoroughly aware of the complications associated with positive-pressure ventilation[10] and suctioning procedures.[11] The CSSC may have a more suitable place in subacute care where patients require only basic ventilatory support, rather than in acute critically ill patients.

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The authors respond:

We appreciate the interest in our article shown by Mr Lebowitz and Mazzagatti; and the points they make are important to the topic of closed-system suctioning. However, the key point of our article was to assist practitioners with proper diagnosis using the chest radiograph and to point out the importance of quick assessment and treatment of the patient.

As we stated, a number of questions can be asked about this particular incident. Because our patient required life support at the time of the incident, investigation during the incident was not possible. We do agree that a number of questions should be asked as to how this particular incident could have occurred, but must stipulate that little evidence exists to suggest a particular reason has more merit than another.

The possibilities of why a suction catheter might exit through a murphy eye could include (1) the fact that this was a directional tipped suction catheter; (2) the possibility of inadequate hydration

in the patient promoting mucus plugging; (3) patient movement during the suctioning procedure; or even (4) manipulation of the suction catheter tip by mucus moving in an upward direction through an open-system suction catheter. Unfortunately, without further testing and evaluation of all types of suction catheters, the exact reason for this incident cannot be known; nor can it be known whether the suction catheter, when left in the tube while the patient was being evaluated, caused intrinsic PEEP.

As we stated in our article, the main point is that this particular type of incident can and did occur. We suppose that this could happen with any catheter given the right circumstances. More importantly we would prefer to stress again that the patient's ventilation was uninterrupted throughout the period of assessment and treatment—an impossibility with an open-system catheter. This is not a reason for recommending that closed-system suction catheters are appropriate for all patients, but it was a side benefit in the case we reported.

We agree with our colleagues that further study of all artificial airways and the relationship of patient movement, expiratory pressures, and suction-catheter design is needed.

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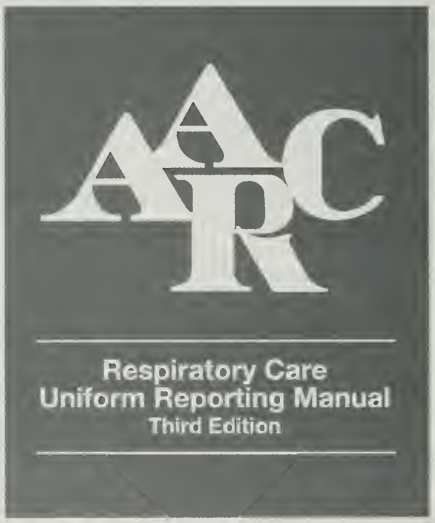

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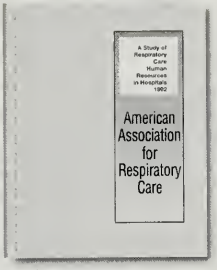

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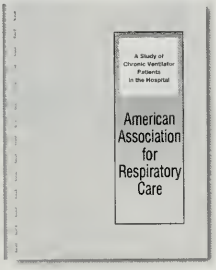

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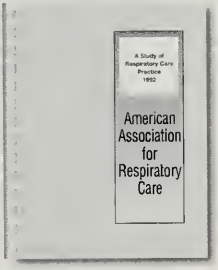

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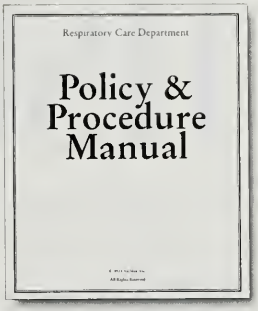

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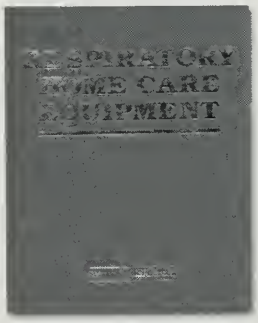

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Item CS15 $10 each
($15 nonmembers)

Calculation and Preparation of Respiratory Medications
Teaches you how to calculate and prepare percentage solutions, ration solutions, solutions prepared from solutes less than 100 percent in strength, and how to prepare dosages from powdered drugs.
Item CS16 $10 each
($15 nonmembers)

Microbiology for Respiratory Therapy: A Review of Microbial Growth and Cross-Contamination
Provides an overview of microbiology in respiratory care, including groups and characteristics of microbes, requirements for microbial growth, cross-contamination, and prevention of transmission.
Item CS17 $9 each
($14 nonmembers)

Classification of Mechanical Ventilators I
Outlines the basic concepts of ventilator classification and a mathematical model of the respiratory system that provides the basis for classifying ventilator control systems. Also teaches the specific criteria for determining whether a ventilator primarily controls pressure, volume, or flow.
Item CS18 $10 each
($15 nonmembers)

Classification of Mechanical Ventilators II
You will learn detailed information about the control of ventilation in terms of switching from inspiration to expiration. You will also be introduced to the common drive mechanisms used in various mechanical devices.
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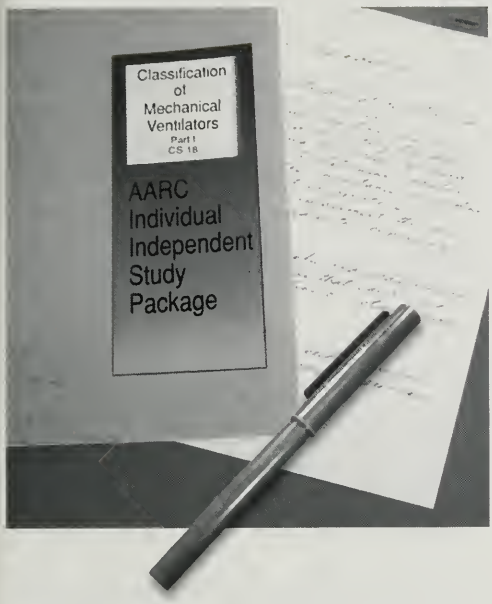

Classification of Mechanical Ventilators III
Explores the output waveforms that ventilators produce and their clinical implications. Instructs in the various modes of ventilation in terms of the specific combinations of control characteristics along with ventilator performance testing and the practical application of ventilator classification.
Item CS20 $10 each
($15 nonmembers)

Ventilation/Perfusion Relationships in Health and Disease
Covers the different degrees of hypoxia commonly encountered in patients with pulmonary disease. Focuses on ventilation/perfusion abnormalities, which account for much of the severe hypoxia in COPD, with alveolar hypoventilation also a contributing factor.
Item CS21 $10 each
($15 nonmembers)

Patient Evaluation

Pulmonary Function Assessment I: Basic Screening Studies
Understand simple spirometry results, the definition of obstructive and restrictive pulmonary disorders, and the basic pathology involved in each. Covers the four reasons for simple spirometry tests, the common parameters of lung function, and the results that are indicative of obstructive and restrictive pulmonary disorders.
Item PE3 $8 each
($13 nonmembers)

Pulmonary Function Assessment II: Bedside Studies
Familiarizes you with the use and interpretation of bedside pulmonary function tests. Learn how pulmonary function test results are used to assess ventilatory ability and which tests are commonly used. Also learn the measuring instrument required for each test, how it is performed, and what is significant about the results.
Item PE4 $7 each
($12 nonmembers)

Pulmonary Function Assessment III: Lung Volume Determination and Closing Volume Studies
Assists in the recall of the eight subdivisions of total lung volume and their individual characteristics in health and disease. Discusses the measurement of lung volume by nitrogen washout, helium dilution, and closing volume techniques.
Item PE5 $7 each
($12 nonmembers)

Body Plethysmography
Explains the theory of body plethysmography and its use in the measurement of FRC and airway resistance. Defines and describes Boyle's Law, thoracic volume, airway resistance and its normal values, and the measurement of airway resistance.
Item PE6 $9 each
($14 nonmembers)

Sources of Error in the Determination of Blood Gas Values and pH
Familiarizes you with the errors that may occur in the analysis of blood gases and pH. These are often the most important laboratory data used in the diagnosis and treatment of pulmonary disease, and errors in these values can result in deleterious effects on patient care.
Item PE7 $10 each
($15 nonmembers)

Temperature Adjustment of Blood Gases and pH
Teaches you the effects of abnormal body temperature on blood gas and pH values. Blood gas values and pH are determined at 37 degrees Celsius, and this package teaches you how to adjust these values.
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Updated! Plotting Static and Dynamic Compliance Curves During Mechanical Ventilation
Learn how to compute and record static compliance curves and dynamic characteristics. Also learn the procedure of obtaining pressure-volume measurements and interpret the compliance characteristics measurements.
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($15 nonmembers)

Arterial Blood Gas Interpretation
Teaches you ABG interpretation in order that the prescribed therapy can be administered in a knowledgeable manner. Describes a systematic method that allows you to correctly classify the acid/base dysfunction and to relate the diagnosis concisely and coherently.
Item PE10 $10 each
($15 nonmembers)

Clinical Practice

Chest Tubes and Pleural Drainage
Helps you understand the purpose of pleural drainage, how it might affect the patient's respiratory status, and what precautions you must take when working with patients who are receiving pleural drainage.
Item CP3 $10 each
($15 nonmembers)

Tracheal Intubation I: Upper Airway Anatomy and Goals of Intubation
After completing this IISP, you will understand the rationale for tracheal intubation and be able to identify the important landmarks of upper airway anatomy.
Item CP4 $7 each
($12 nonmembers)

Tracheal Intubation II: Routes of Intubation
Describes the four routes of tracheal intubation and some advantages and hazards of each. Also presents the process for selecting the most suitable route in a given situation.
Item CP5 $7 each
($12 nonmembers)

Tracheal Intubation III: Equipment Procedures for Intubation
Covers the selection of the proper equipment necessary to perform endotracheal intubation and to ensure that they are in working order.
Item CP6 $8 each
($13 nonmembers)

Respiratory Management of Neuromuscular Crisis
Teaches respiratory management of patients with ventilatory failure caused by a neuromuscular disorder. Provides a basic understanding of how neuromuscular conditions lead to ventilatory insufficiency and the considerations to be taken when working with these patients.
Item CP7 $7 each
($12 nonmembers)

Respiratory Management of Flail Chest
This study package helps you increase your understanding of the pathophysiology of flail chest and the respiratory management of patients who have sustained chest wall trauma that results in a flail chest.
Item CP8 $10 each
($15 nonmembers)

Respiratory Management of Head Trauma
Teaches identification of the five physical signs indicative of head trauma and explains the development of respiratory failure secondary to trauma. Also discusses airway management, drug therapy, ventilator parameters, acid-base status, and measures to be taken to maintain the appropriate pH, P_{aCO_2} and P_{aO_2}.
Item CP9 $10 each
($15 nonmembers)

RESPIRATORY CARE

Manuscript Preparation Guide

General Information

RESPIRATORY CARE welcomes original manuscripts related to respiratory care and prepared according to these Instructions. Manuscripts are blinded and reviewed by professionals who are experts in their fields. Authors are responsible for all aspects of the manuscript and receive galleys to proofread before publication. Each accepted manuscript is copyedited so that its message is clear and it conforms to the Journal's style. Published papers are copyrighted by Daedalus Inc and may not be published elsewhere without permission.

Editorial consultation is available at any stage of planning or writing. On request, specific guidance is provided for all publication categories. These Instructions and related materials are available. Write to RESPIRATORY CARE, 11030 Ables Lane, Dallas TX 75229-4593, call (214) 243-2272, or fax (214) 484-6010.

Publication Categories & Structure

Research Article: A report of an original investigation (a study). It includes a Title Page, Abstract, Introduction, Methods, Results, Discussion, Conclusions, Product Sources, Acknowledgments, References, Tables, Appendices, Figures, and Figure Captions.

Evaluation of Device/Method/Technique: A description and evaluation of an old or new device, method, technique, or modification. It has a Title Page, Abstract, Introduction, Description of Device/Method/Technique, Evaluation Methods, Evaluation Results, Discussion, Conclusions, Product Sources, Acknowledgments, References, Tables, Appendices, Figures, and Figure Captions.

Case Report: A report of a clinical case that is uncommon, or was managed in a new way, or is exceptionally instructive. All authors must be associated with the case. A case-managing physician must either be an author or furnish a letter approving the manuscript. Its components are Title Page, Abstract, Introduction, Case Summary, Discussion, References, Tables, Figures, and Figure Captions.

Review Article: A comprehensive, critical review of the literature and state-of-the-art summary of a pertinent topic that has been the subject of at least 40 published research articles. Title Page, Outline, Introduction, Review of the Literature, Summary, Acknowledgments, References. Tables, Appendices, and Figures and Captions may be included.

Overview: A critical review of a pertinent topic that has fewer than 40 published research articles.

Update: A report of subsequent developments in a topic that has been critically reviewed in this Journal or elsewhere.

Point-of-View Paper: A paper expressing personal but substantiated opinions on a pertinent topic. Title Page, Text, References, Tables, and Illustrations may be included.

Special Article: A pertinent paper not fitting one of the foregoing categories may be acceptable as a Special Article. Consult with the Editor before writing or submitting such a paper.

Editorial: A paper drawing attention to a pertinent concern; it may present an opposing opinion, clarify a position, or bring a problem into focus.

Letter: A signed communication about prior publications in this Journal or about other pertinent topics. Tables and illustrations may be included. Mark "For publication."

Blood Gas Corner: A brief, instructive case report involving blood-gas values—with Questions, Answers, and Discussion.

Drug Capsule: A mini-review paper about a drug or class of drugs that includes discussions of pharmacology, pharmacokinetics, and pharmacotherapy.

Kittredge's Corner: A brief description of the operation of respiratory care equipment—with information from manufacturers and editorial comments and suggestions.

PFT Corner: Like Blood Gas Corner, but involving pulmonary function tests.

Test Your Radiologic Skill: Like Blood Gas Corner, but involving pulmonary medicine radiography and including one or more radiographs, may involve imaging techniques other than conventional chest radiography.

Review of Book, Film, Tape, or Software: A balanced, critical review of a recent release.

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Article in a journal carrying pagination throughout volume:

1. Rau JL, Harwood RJ. Comparison of nebulizer delivery methods through a neonatal endotracheal tube: a bench study. Respir Care 1992;37(11):1233-1240.

Article in a publication that numbers each issue beginning with Page 1:

2. Bunch D. Establishing a national database for home care. AARC Times 1991;15(Mar):61,62,64.

Corporate author journal article:

3. American Association for Respiratory Care. Criteria for establishing units for chronic ventilator-dependent patients in hospitals. Respir Care 1988;33(11):1044-1046.

Article in journal supplement: (Journals differ in their methods of numbering and identifying supplements. Supply sufficient information to promote retrieval.)

4. Reynolds HY. Idiopathic interstitial pulmonary fibrosis. Chest 1986;89(3, Suppl):139S-143S.

Abstract in journal: (Abstracts citations are to be avoided. Those more than 3 years old should not be cited.)

5. Stevens DP. Scavenging ribavirin from an oxygen hood to reduce environmental exposure (abstract). Respir Care 1990;35(11): 1087-1088.

Editorial in journal:

6. Enright P. Can we relax during spirometry? (editorial). Am Rev Respir Dis 1993;148(2):274.

Editorial with no author given:

7. Negative-pressure ventilation for chronic obstructive pulmonary disease (editorial). Lancet 1992;340(8833):1440-1441.

Letter in journal:

8. Aelony Y. Ethnic norms for pulmonary function tests (letter). Chest 1991;99(4):1051.

Paper accepted but not yet published:

9. Hess D. New therapies for asthma. Respir Care (year, in press).

Personal author book: (For any book, specific pages should be cited whenever possible.)

10. DeRemee RA. Clinical profiles of diffuse interstitial pulmonary disease. New York: Futura, 1990:76-85.

Corporate author book:

11. American Medical Association Department of Drugs. AMA drug evaluations, 3rd ed. Littleton CO: Publishing Sciences Group, 1977.

Chapter in book with editor(s):

12. Pierce AK. Acute respiratory failure. In: Guenter CA, Welch MH, editors. Pulmonary medicine. Philadelphia: JB Lippincott, 1977.

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Drugs. Identify precisely all drugs and chemicals used, giving generic names, doses, and routes of administration. If desired, brand names may be given in parentheses after generic names. Drugs should be listed on the product-sources page.

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Units of Measurement. Express measurements of length, height, weight, and volume in metric units appropriately abbreviated; temperatures in degrees Celsius; and blood pressures in millimeters of mercury (mm Hg). Report hematologic and clinical-chemistry measurements in conventional metric and in SI (Systémé Internationale) units. Show gas pressures (including blood gas tensions) in torr. List SI equivalent values, when possible, in brackets following non-SI values—for example, "PEEP, 10 cm H_2O [0.981 kPa]." For conversion to SI, see RESPIRATORY CARE 1988;33(10):861-873 (Oct 1988) and 1989;34(2):145 (Feb 1989).

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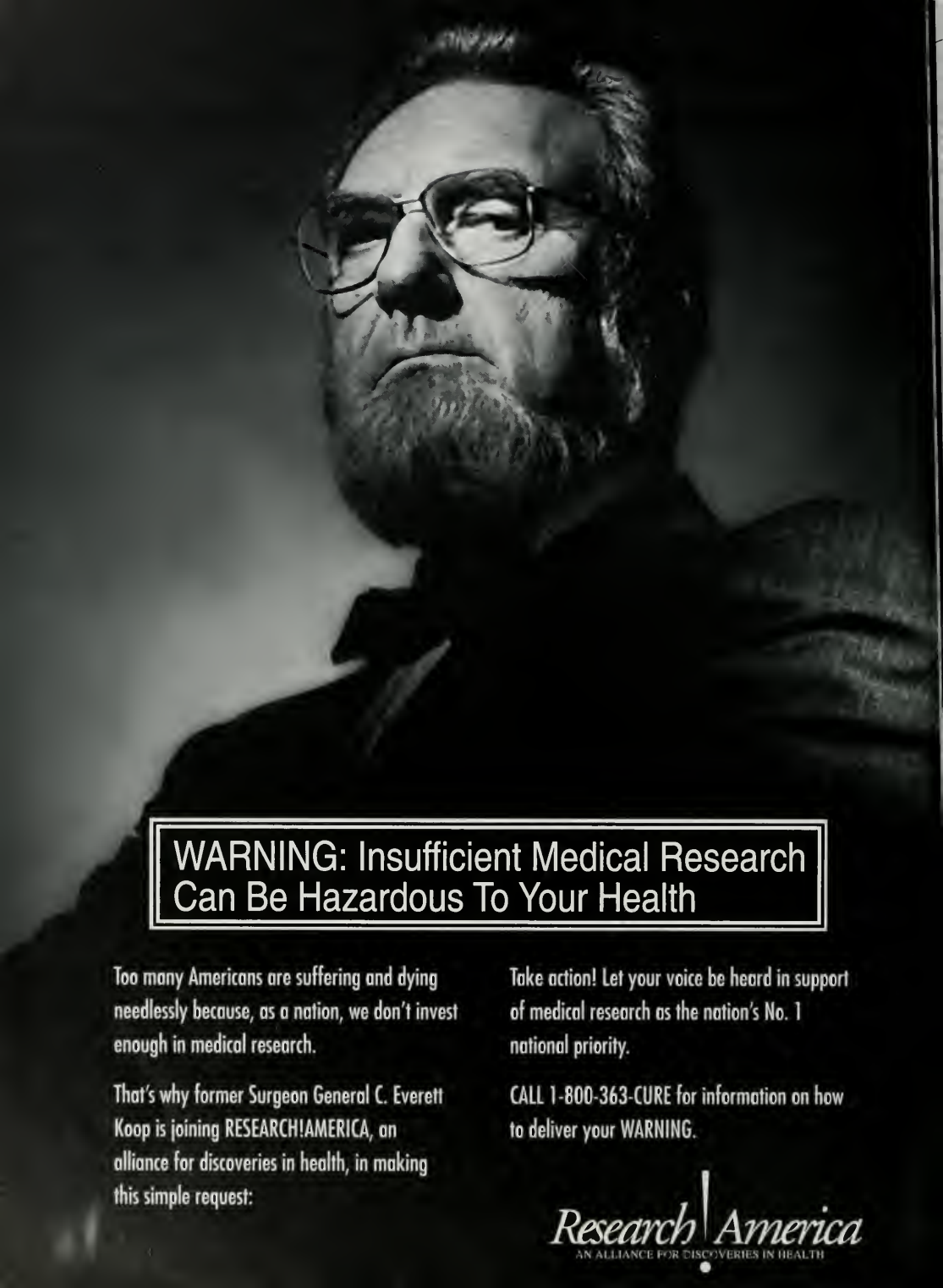
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James K Stoller MD

Identifying a Clinical Question and Formulating a Hypothesis

Shelley Mishoe PhD RRT

A Vignette: What Is a Null Hypothesis?

Dean Hess PhD RRT

Reviewing the Literature and Finding a Mentor

Joseph L Rau Jr PhD RRT

A Vignette: The p value—Just What Is It?

Dean R Hess PhD RRT

Validating Patient-Driven Protocols—Choosing a Design

Charles G Durbin Jr MD

A Vignette: Getting Your Abstract Accepted

Kaye Weber MS RRT

Plan to attend on Tuesday, December 5, 1995 9:00-11:00 am

New Products & Services

News releases about new products and services will be considered for publication in this section. There is no charge for these listings. Send descriptive release and glossy black and white photographs to RESPIRATORY CARE Journal, New Products and Services Dept, 11030 Ables Lane, Dallas TX 75229-4593.

COMPUTER WORK STATION. Ergotron Inc, maker of ergonomic computer work stations, offers The Command Post, a computer/video display mounting column. According to Ergotron, the new work center may be placed on the floor or suspended overhead for optimal use of floor space. The workstation allows each operator to adjust the monitor to the correct height, distance and angle. Several installation options and accessories, such as a foot rest, collapsible work surface, and keyboard holders, are available. Write to Ergotron Inc, Dept RC, 3450 Yankee Drive, Suite 100, Eagan MN 55121. Remember to mention RESPIRATORY CARE when you call (800) 888-8458.

PEDIATRIC WARMING BLANKETS. The Care Quilt® and the CareDrape® blankets are offered by Mallinckrodt Medical. The blankets are designed to enhance convective warming of pediatric patients during hospitalization, according to Mallinckrodt. The blankets are part of the manufacturer's Warm-Touch® Patient Warming System that uses high-flow convective air warming to regulate patient body temperature and help prevent hypothermia during surgery and recovery. For more details, mention RESPIRATORY CARE when you call (314) 895-2000, or write to Mallinckrodt Medical Inc, Dept RC, 675 McDonnell Boulevard, PO Box 5840, St Louis MO 63134.

GENERIC SYRUP. Dey Laboratories announces the availability of Albuterol Sulfate Syrup, 2 mg/5 mL in 16 fluid ounce plastic bottles. According to Dey, the generic Albuterol Sulfate Syrup is "AA" rated (pharmaceutically and therapeutically equivalent to Proventil® and Ventolin® Syrups). The syrup is used for the relief of bronchospasm in adults and children two years and older with reversible obstructive airway disease. The syrup contains no saccharine or sorbitol and has a strawberry flavor. For information about contraindications and common side effects, call Dey Laboratories at (800) 755-5560. Please mention RESPIRATORY CARE when you call.

APPOINTMENT SOFTWARE. TeleVox Software Inc introduces HouseCalls, a PC-based program that uses the professional's existing appointment scheduling software and appointment scheduler with a digital voice board designed to deliver personalized patient messages. According to TeleVox, with a PC and a telephone, HouseCalls can offer the medical professional a personal, reliable, and economical way to schedule and confirm appointments. By using special features in the system, personalized messages can be made. For a special message about the HouseCalls system dial (800) 426-6184. For information about the software program, write to TeleVox Software Inc, Dept RC, 1120 Hillcrest Road, Suite 2A, Mobile AL 36695, or call (800) 644-4266. Please mention RESPIRATORY CARE when calling.

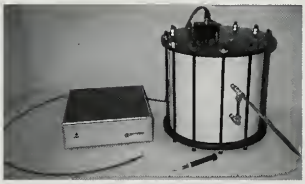
FLOW-CONTROL REGULATORS. Victor Medical announces the availability of the FS-Series regulators designed for durability and patient positioning. According to the manufacturer, the regulators—available in 5 models—include 11 flow positions in 3 flow ranges. In addition, the new design features a 90° body-yoke arrangement with swivel to aid patient positioning and to prevent regulator knob and barb damage. The regulators include high-visibility 2-color gauges, a rear outlet barb, and a dual-use yoke washer. All regulators are constructed of lightweight, chrome-plated brass for extra durability. For details, call Victor Medical at (800) 382-8187. Don't forget to mention RESPIRATORY CARE.

DISINFECTANT/CLEANER. BioSafety Systems announces the addition of Envirocide® Disinfectant. Envirocide is an effective, ready-to-use, broad-spectrum disinfectant/cleaner for use on various surfaces. According to BioSafety, Envirocide is safe for use on delicate medical and surgical equipment and instrumentation and isolation and critical care areas where environmental infection control is necessary. For a free sample, write to BioSafety Systems, Dept RC, 10225 Willow Creek Road, San Diego CA 92131, or call (800) 421-0509. Remember to mention RESPIRATORY CARE when calling.

SLEEP MONITORING DEVICES. EPMSystems improves the Easyflow Airflow Sensor™. This sensor is smaller and more comfortable for patients, provides recording flexibility with no batteries or interface box, and is available in three sizes. According to EPMSystems, several sleep-monitoring products have also been improved from the suggestions of sleep specialists. In addition, the company has added a family of body-position sensors. The Tracker™ features reliable detection of 8 body positions during sleep and optional auditory signal, direct input to recorder's headbox, AC pattern output for easy visual recognition, and continuous DC output pattern for computer recording systems. Enhanced versions included Tracker Plus™, capable of storing data from two weeks of continuous monitoring and Mini Tracker™, a smaller model ideal for portable monitoring. For a product catalog, write to EPMSystems, Dept RC, 5212 Highberry Woods Road, Midlothian VA 23112, or call (804) 739-7022. Remember to mention RESPIRATORY CARE when you call.

DISPOSABLE FULL-FACE MASK. Respironics Inc introduces the Spectrum™ Disposable Full-Face Mask. According to Respironics the face mask is ideal for adult patients requiring CPAP or bi-level therapy for the treatment of Obstructive Sleep Apnea. As an alternative to nasal masks, the new design may help alleviate the dryness and discomfort sometimes caused by nasal-interface leaks. The Full-Face Mask includes a quick-release feature for quick removal and a magnetic air-entrainment-valve that opens the circuit to room air in the event of a circuit disconnection or power outage. Available in 4 sizes, the mask is designed for single-patient use. The mask is also available with Convertible Headgear, specifically for use with the Full-Face Mask. Write to Respironics, Dept RC, 1001 Murry Ridge Drive, Murrysville PA 15668 for more details. Please mention RESPIRATORY CARE when you call (412) 733-0200.

WAVEFORM DEFINITION GUIDE. Fogg System Company Inc offers collections of waveforms—All Wave™ Guides to Waveform Definition. According to Fogg, the guides graphically illustrate 121 shapes per page, arranged in 11 rows by 11 columns. The selected shapes may be used to define waveforms for arbitrary waveform generators and for other applications, such as the creation of waveform information to evaluate data analysis. Other applications include physiologic waveform simulators for blood pressure, electrocardiogram, respiration, temperature, cardiac output, and pulse oximetry. The All Wave collection may be used with Fogg's M311 ECG Simulator and All Wave Software. For details, write to Fogg System Company Inc, Dept RC, 15592 East Batavia Drive, Aurora CO 80011. Or, mention RESPIRATORY CARE when you call (800) 525-0292.



GAS MIXER. Columbus Instruments International Corporation introduces the ppm (parts per million) Gas Mixer. According to the company, the mixer employs the simple principle of mixing two known volumes of gas at ambient barometric pressure. The ppm Gas Mixer can provide 20 liters of calibrated gas mixture and is useful in situations where the minority component is < 1%. The calibrated gas mixture may be transferred to the user's sensor at an adjustable rate of 0-3 L/min. The mixer also has a set of gas valves and an electric, gas-tight air pump. For additional information, write to Columbus Instruments, Dept RC, PO Box 44049, Columbus OH 43204. Or mention RESPIRATORY CARE when you call (614) 276-0861.

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Notices of competitions, scholarships, fellowships, examination dates, new educational programs, and the like will be listed here free of charge. Items for the Notices section must reach the Journal 60 days before the desired month of publication (January 1 for the March issue, February 1 for the April issue, etc). Include all pertinent information and mail notices to RESPIRATORY CARE Notices Dept, 11030 Ables Lane, Dallas TX 75229-4593.

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	July 20, 1996	100	(new applicant)
	Application Deadline: May 1, 1996	60	(reapplicant)
	November 9, 1996	100	(new applicant)
	Application Deadline: September 1, 1996	60	(reapplicant)
RRT Examination	June 1, 1996	100	Written only (new applicant)
	Application Deadline: February 1, 1996	60	Written only (reapplicant)
		110	CSE only (all applicants)
	December 7, 1996	210	Both (new applicant)
	Application Deadline: August 1, 1996	170	Both (reapplicant)
CPFT Examination	June 1, 1996	110	(new applicant)
	Application Deadline: April 1, 1996	80	(reapplicant)
RPFT Examination	December 7, 1996	160	(new applicant)
	Application Deadline: September 1, 1996	130	(reapplicant)
Perinatal/Pediatric Respiratory Care	March 9, 1996	160	(new applicant)
	Application Deadline: November 1, 1995	130	(reapplicant)

For information about other services or fees, write to the
National Board for Respiratory Care, 8310 Nieman Road, Lenexa KS 66214, or call (913) 599-4200.

1995 Publication Awards

$1,000 Radiometer Awards for Best Feature Articles from Test Your Radiologic Skill, Blood Gas Corner, Kittredge's Corner, and PFT Corner accepted for publication from November 1994 through October 1995. Sponsored by Radiometer America (Divided equally among three winners).

$1,000 Best Papers by 1994 OPEN FORUM Participants Who Have Never Published as First Author. Authors must present the abstract at the Annual Meeting and submit a paper based on the abstract to the Editorial Office by November 1, 1995. Sponsored by Allen & Hanburys (Two winners - $500 each).

$2,000 Best Papers on OPEN FORUM Presentation. Papers accepted for publication from November 1994 through October 1995 based on any OPEN FORUM presentation. Sponsored by Allen & Hanburys (Two winners - $1,000 each).

$2,000 Best Paper Published in RESPIRATORY CARE. Original Study, Evaluation, or Case Report November 1994 through October 1995. Sponsored by Allen & Hanburys.

$2,000 Dr Allen DeVilbiss Technology Paper Award. Best paper published from November 1994 through October 1995 that addresses new technology or a new application of current technology in respiratory care (Plus travel expenses to the AARC Annual Convention & Exhibition).

FACE TO FACE WITH CHANGE

FACE TO FACE WITH CHANGE

AARC 41st Annual Convention & Exhibition
Orlando, Florida
December 2-5, 1995

Registration deadline is
November 11, 1995.
For information, call (214) 243-2272

MEDWATCH

FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

Page ____ of ____

Form Approved: OMB No. 0910-0291 Expires: 12/31/94
See OMB statement on reverse

FOA Use Only (RESP CARE)

Triage unit sequence #

Patient information

1. Patient identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
n confidence		☐ female ☐ male	____ lbs or ____ kgs

Adverse event or product problem

1. ☐ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
   - ☐ death ____ (mo/day/yr)
   - ☐ life-threatening
   - ☐ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other: ____

3. Date of event (mo/day/yr)

4. Date of this report (mo/day/yr)

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1
   #2

2. Dose, frequency & route used
   #1
   #2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   #1
   #2

4. Diagnosis for use (indication)
   #1
   #2

5. Event abated after use stopped or dose reduced
   #1 ☐ yes ☐ no ☐ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
   #1
   #2

7. Exp. date (if known)
   #1
   #2

8. Event reappeared after reintroduction
   #1 ☐ yes ☐ no ☐ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
   – –

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
   - ☐ health professional
   - ☐ lay user/patient
   - ☐ other: ____

5. Expiration date (mo/day/yr)

6.
   model # ____
   catalog # ____
   serial # ____
   lot # ____
   other # ____

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
   ☐ yes ☐ no ☐ returned to manufacturer on ____ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

2. Health professional? ☐ yes ☐ no

3. Occupation

4. Also reported to
   - ☐ manufacturer
   - ☐ user facility
   - ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

A Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

ADVICE ABOUT VOLUNTARY REPORTING

Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

Report even if:

- you're not certain the product caused the event
- you don't have all the details

Report product problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling

How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-800-822-7967 for a VAERS form for vaccines

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

The public reporting burden for this collection of information has been estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send your comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Reports Clearance Officer, PHS
Hubert H. Humphrey Building,
Room 721-B
200 Independence Avenue, S.W.
Washington, DC 20201
ATTN: PRA

and to:
Office of Management and Budget
Paperwork Reduction Project
(0910-0230)
Washington, DC 20503

Please do NOT return this form to either of these addresses.

FDA Form 3500-back

Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use $300

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MEDWATCH
The FDA Medical Products Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

1996 Call for Abstracts

RESPIRATORY CARE • OPEN FORUM

The American Association for Respiratory Care and its science journal, RESPIRATORY CARE, invite submission of brief abstracts related to any aspect of cardiorespiratory care. The abstracts will be reviewed, and selected authors will be invited to present posters at the OPEN FORUM during the AARC Annual Meeting in San Diego, California, November 3-6 1996. Accepted abstracts will be published in the October 1996 issue of RESPIRATORY CARE. Membership in the AARC is not required for participation.

SPECIFICATIONS—READ CAREFULLY!

An abstract may report **(1) an original study, (2) the evaluation of a method or device, or (3) a case or case series.** Topics may be aspects of adult acute care, continuing care/rehabilitation, perinatology/pediatrics, cardiopulmonary technology, or health-care delivery. The abstract may have been presented previously at a local or regional—but not national—meeting and should not have been published previously in a national journal. The abstract will be the only evidence by which the reviewers can decide whether the author should be invited to present a poster at the OPEN FORUM. Therefore, *the abstract must provide all important data, findings, and conclusions.* Give specific information. Do not write such general statements as "Results will be presented" or "Significance will be discussed."

Essential Content Elements

Original study. Abstract *must* include (1) Background: statement of research problem, question, or hypothesis; (2) Method: description of research design and conduct in sufficient detail to permit judgment of validity; (3) Results: statement of research findings with quantitative data and statistical analysis; (4) Conclusions: interpretation of the meaning of the results.

Method/device evaluation. Abstract *must* include (1) Background: identification of the method or device and its intended function; (2) Method: description of the evaluation in sufficient detail to permit judgment of its objectivity and validity; (3) Results: findings of the evaluation; (4) Experience: summary of the author's practical experience or a lack of experience; (5) Conclusions: interpretation of the evaluation and experience. Cost comparisons should be included where possible and appropriate.

Case report. Abstract *must* report a case that is uncommon or of exceptional educational value and must include (1) Introduction: Relevant basic information important to understanding the case. (2) Case Summary: Patient data and response, details of interventions. (3) Discussion: Content should reflect results of literature review. The author(s) should have been actively involved in the case and a case-managing physician must be a co-author or must approve the report.

Abstract Format and Typing Instructions

Accepted abstracts will be photographed. The first line of the abstract should be the title in all capital letters. Title should explain content. Follow title with names of all authors (including credentials), institution(s), and location. Underline presenter's name. Type or electronically print the abstract *single spaced in the space provided on the abstract blank.* Insert only one letter space between sentences. Text submission on diskette is encouraged but must be accompanied by a hard copy. Identifiers will be masked (blinded) for review. Make the abstract all one paragraph. Data may be submitted in table form, *and simple figures may be included provided they fit within the space allotted.* No figures, illustrations, or tables are to be attached to the abstract form. Provide all author information requested at the bottom of abstract form. A clear photocopy of the abstract form may be used. Standard abbreviations may be employed without explanation. A new or infrequently used abbreviation should be preceded by the spelled-out term the first time it is used. Any recurring phrase or expression may be abbreviated, if it is first explained. Check the abstract for (1) errors in spelling, grammar, facts, and figures; (2) clarity of language; and (3) conformance to these specifications. An abstract not prepared as requested may not be reviewed. Questions about abstract preparation may be telephoned to the editorial staff of RESPIRATORY CARE at (214) 243-2272.

Deadline Allowing Revision

Authors may choose to submit abstracts early. Abstracts postmarked by February 11, 1996 will be reviewed and the authors notified by letter only to be mailed by March 22, 1996. Rejected abstracts will be accompanied by a written critique that should, in many cases, enable authors to revise their abstracts and resubmit them by the final deadline (April 28, 1996).

Final Deadline

The mandatory Final Deadline is April 28 (postmark). Authors will be notified of acceptance or rejection *by letter only.* These letters will be mailed by July 15, 1996.

Mailing Instructions

Mail (Do not fax!) 2 clear copies of the completed abstract form, diskette (if possible), and a stamped, self-addressed postcard (for notice of receipt) to:

RESPIRATORY CARE OPEN FORUM
11030 Ables Lane
Dallas TX 75229-4593

1996 Respiratory Care Open Forum
Abstract Form

18.8 cm or 7.4"

13.9 cm or 5.5"

1. Title must be in all upper case (capital) letters, authors' full names and text in upper and lower case.
2. Follow title with all authors' names including credentials (underline presenter's name), institution, and location.
3. Do not justify (ie, leave a 'ragged' right margin).
4. **Do not use type size less than 10 points.**
5. All text, tables, and figures must fit into the rectangle shown.
6. Submit 2 clean copies. This form may be photocopied if multiple abstracts are to be submitted.

Mail original & 1 photocopy (along with postage-paid postcard) to

Respiratory Care Open Forum
11030 Ables Lane
Dallas TX 75229-4593

Early deadline is February 11, 1996 (postmark)

Final deadline is April 28, 1996 (postmark)

Presenter

Name & Credentials

Mailing Address

Voice Phone & Fax

Corresponding Author If Different from Presenter

Name & Credentials

Mailing Address

Voice Phone & Fax

Not-for-profit organizations are offered a free advertisement of up to eight lines to appear, on a space-available basis, in Calendar of Events in RESPIRATORY CARE. Ads for other meetings are priced at $5.50 per line and require an insertion order. Deadline is the 20th of the month two months preceding the month in which you wish the ad to run. Submit copy and insertion orders to Calendar of Events, RESPIRATORY CARE, 11030 Ables Lane, Dallas TX 75229-4593.

Calendar of Events

AARC & AFFILIATES

October 5–6 in Albany, New York. The Northeastern Chapter of the NYSSRC hosts its Annual Teaching Day at the Desmond Inn. Featured topics include lung reduction surgery, management of the difficult airway, and current concepts in pediatric asthma therapy. Other events include Sputum Bowl competitions and an open forum panel of area pulmonologists. Contact Dawn Bentley or Bill Wenzel, Respiratory Care Department, St Peter's Hospital, 315 S Manning Blvd, Albany NY 12208, (518) 454-1062.

October 5–6 in Jackson, Mississippi. The MSRC presents its Annual State Convention and Exhibition at the Harvey Hotel. Managed care, patient-care protocols, high-frequency ventilation, and body plethysmography are among the featured topics. Registration for AARC members is $80. Contact Educational Chairperson Rhonda Dancy, Route 2, Box 1, Lambert MS 38643, (601) 326-4815.

October 11–13 in Columbus, Ohio. The OSRC announces its 19th Annual Meeting at the Holiday Inn Conference Center at Worthington. Featured discussions include clinical care of the patient and current topics affecting respiratory care. Breakout sessions are available in management, student education, and blood gas laboratory management. CRCE credit has been requested. Contact Dan Wine, Program Planning Chairman, Respiratory Care Department, Grady Memorial Hospital, 561 W Central Ave, Delaware OH 43015, (614) 368-5315.

October 13 in Colorado Springs, Colorado. The Southern Chapter of the CSRC presents the 2nd Annual Southern Colorado Pulmonary Medicine Symposium at the Holiday Inn, Garden of the Gods. Topics include neonatal ventilation, partial liquid ventilation of the adult, current trends in sleep disorder management, and reactive airways disorders in respiratory therapists. Registration is $15 and includes lunch; participants can earn up to 5 hours of CRCE credit. Contact Barry Beard at (719) 776-5211.

October 13 in Houston, Texas. The South Texas Region announces a TSRC seminar at the Houston Community College, Southeast College Annex Building. Topics include restructuring, clinical assessments, and case study presentations. Six hours of CRCE credit have been requested. Contact Romar Reyes at (713) 746-5328.

October 13 in Pikeville, Tennessee. The TSRC presents its 2nd Annual Fall Fest at Fall Creek Falls State Park. Topics include benchmarking and developing critical pathways. Contact Colleen Schabacker at (615) 384-1731.

October 13–14 in Boise, Idaho. The ISRC hosts its annual educational fall meeting, "Surviving Change," at the Red Lion, Riverside, in conjunction with the 2nd Annual John Butler Lung Conference. The fee for AARC members is $30; CRCE credit has been requested. Contact Leslie Ann Mulder at (208) 336-3391.

October 20 in Uniondale, New York. The Southeastern Chapter of the New York State Society for Respiratory Care hosts its 27th Annual Symposium at the Marriott Hotel. The symposium, "The Wheel of Change—Are We Prepared?" features a managers' breakfast, 50 exhibitor booths, and the annual awards luncheon. Contact Ralph Cavallo at (212) 523-3101 or Michael Karol at (718) 470-7680.

October 25–26 in Sturbridge, Massachusetts. The MSRC presents its 18th Annual Meeting at the Sturbridge Host Hotel and Conference Center. Participants can earn 10 hours of CRCE credit. Contact Cynthia Bowman, 945 Concord St, Framingham MA 01701, (508) 620-4505.

January 26, 1996 in Austin, Texas. The TSRC announces its Annual Winter Forum at the Marriott Hotel on 11th Street. Contact the TSRC Executive Office in Dallas at (214) 680-2455, or contact Mimi Bartel in Houston at (713) 746-5354.

OTHER MEETINGS

October 3 in Harrisburg, Pennsylvania. Holy Spirit Hospital presents "Breath by Breath, Step by Step," an educational seminar at the Holiday Inn East. The seminar is designed to improve clinical and communication skills in both acute care and pulmonary rehabilitation. Surgical options for COPD is the main topic. Participants can earn 4 hours of CRCE credit. Contact Mike Portzine at (717) 763-2832.

October 12–15 in Minneapolis, Minnesota. The American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) announces its 10th Annual Meeting, "Building on Success… A Decade of Progress," at the Minneapolis Convention Center. The meeting features 60 exhibitor booths, more than 100 speakers, a banquet on Friday, and a Saturday evening party. CRCE credit has been requested. Contact AACVPR at (608) 831-6989.

October 20 in Atlanta, Georgia. Saint Joseph's Hospital of Atlanta hosts its 12th Annual Respiratory Care Seminar at Saint Joseph's Hospital Auditorium. The seminar focuses on current and future trends in the treatment of respiratory illness. Contact Sandra Mann at (404) 851-7176.

October 30 – November 2 in San Antonio, Texas. The American Association of Homes and Services for the Aging (AAHSA) hosts its 34th Annual Meeting and Exposition – "Embrace the Power of Global Vision" – and offers 168 educational sessions, 4 general sessions, and an exposition of more than 350 companies. Call the AAHSA Annual Meeting Information Line at (202) 508-9400.

November 2 in Reno, Nevada. The American Lung Association (ALA) of Nevada presents the 14th Annual Respiratory Health Conference in the Mack Auditorium at Washoe Medical Center. Contact Tom Jacobs, ALA of Nevada, 6119 Ridgeview Ct, Suite 100, Reno NV 89509, (702) 829-5864.

November 3 in Wilmington, Delaware. The Alfred I duPont Institute's departments of respiratory care, pediatrics, and nursing, in conjunction with the American Lung Association of Delaware, announce the 4th Annual Delaware Pediatric Pulmonary Symposium at the Institute. Participants may earn 5 hours of CRCE credit. Topics include exogenous surfactant, pulmonary circulation physiology, and new concepts in asthma pathogenesis and management. Contact the Alfred I duPont Institute, Medical Education Department, PO Box 269, Wilmington DE 19899, (302) 651-6750.

April 9–15, 1996 in Miami, Florida. The Ventilation Assisted Children's Center (VACC) of Miami Children's Hospital Division of Pulmonology announces its free camp for ventilation-assisted children and their families. Activities include field trips, swimming, games, arts, and crafts. The application deadline for overnight campers is January 5, 1996. Contact Director Moises Simpser or Coordinator Cathy Klein, VACC, Division of Pulmonology, Miami Children's Hospital, 3200 SW 60th Ct, Suite 203, Miami FL 33155-4076, (305) 662-VACC, fax (305) 663-8417.

September 18–21, 1996 in San José, Costa Rica. The Costa Rica Society for Respiratory Therapy presents the 2nd Latin America Congress and Caribbean Congress for Respiratory Therapy. Contact Lic Carlos E Pereira Hidalgo, Apartado 184-1017, San José 2000, San José Costa Rica, (506) 232-8310, fax (506) 232-7786.

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SUBSCRIPTION RATES FOR ASSOCIATIONS. An association may offer individual subscriptions of RESPIRATORY CARE to its members at a reduced rate. The rates based on membership are: $6 per year for 101-500 members; $5.50 for 501-1,500 members; $5 for 1,501-10,000 members; $4 for more than 10,000 members. For information, contact Ray Masferrer at (214) 243-2272.

CHANGE OF ADDRESS. Notify RESPIRATORY CARE as soon as possible of any change in address. Note the subscription number (from the mailing label) and your name, old address, and new address. Allow 6 weeks for the change. To avoid charges for replacement copies of missed issues, requests must be made within 60 days in the US and 90 days in other countries.

MANUSCRIPTS. The Journal publishes clinical studies, method/device evaluations, reviews, and other materials related to cardiopulmonary medicine and research. Manuscripts may be submitted to the Editorial Office, RESPIRATORY CARE, 11030 Ables Lane, Dallas TX 75229-4593. Instructions for authors are printed in every issue. An expanded version of the Instructions is available from the editorial office.

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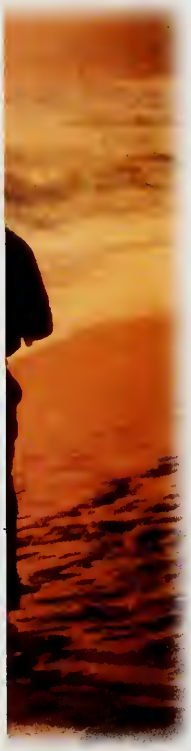
4. ❑ Hosp 100 to 199 beds
5. ❑ Hosp 100 or less beds
6. ❑ Skilled Nursing Facility
7. ❑ Home Care Practice
8. ❑ School

II. Department
A. ❑ Respiratory Therapy
B. ❑ Cardiopulmonary
C. ❑ Anesthesia Service
D. ❑ Emergency Dept

III. Specialty
1. ❑ Clinical Practice
2. ❑ Perinatal Pediatrics
3. ❑ Critical Care
4. ❑ Clinical Research
5. ❑ Pulmonary Function Lab
6. ❑ Home Care/Rehab
7. ❑ Education
8. ❑ Management

IV. Position
A. ❑ Dept Head
B. ❑ Chief Therapist
C. ❑ Supervisor
D. ❑ Staff Technician
E. ❑ Staff Therapist
F. ❑ Educator
G. ❑ Medical Director
H. ❑ Anesthesiologist
I. ❑ Pulmonologist
J. ❑ Other MD
K. ❑ Nurse

V. Are you a member of the AARC?
1. ❑ Yes 2. ❑ No



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2. ❑ Hosp 300 to 499 beds
3. ❑ Hosp 200 to 299 beds
4. ❑ Hosp 100 to 199 beds
5. ❑ Hosp 100 or less beds
6. ❑ Skilled Nursing Facility
7. ❑ Home Care Practice
8. ❑ School

II. Department
A. ❑ Respiratory Therapy
B. ❑ Cardiopulmonary
C. ❑ Anesthesia Service
D. ❑ Emergency Dept

III. Specialty
1. ❑ Clinical Practice
2. ❑ Perinatal Pediatrics
3. ❑ Critical Care
4. ❑ Clinical Research
5. ❑ Pulmonary Function Lab
6. ❑ Home Care/Rehab
7. ❑ Education
8. ❑ Management

IV. Position
A. ❑ Dept Head
B. ❑ Chief Therapist
C. ❑ Supervisor
D. ❑ Staff Technician
E. ❑ Staff Therapist
F. ❑ Educator
G. ❑ Medical Director
H. ❑ Anesthesiologist
I. ❑ Pulmonologist
J. ❑ Other MD
K. ❑ Nurse

V. Are you a member of the AARC?
1. ❑ Yes 2. ❑ No

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For example, the *Peak Inspiratory Flow Monitor* enables you to assess the adequacy of mechanical flow versus patient flow demand and adjust accordingly.

ments on the ventilator you can lessen the chance for auto-PEEP and decrease work to trigger the ventilator.

Also facilitating recovery is our *Predictive Learning Logic*

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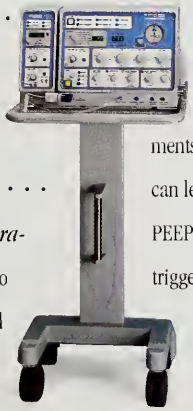

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Using the ***Peak Expiratory Flow Monitor*** can help you determine if a filter is clogged, assess a response to a bronchodilator and observe changes in compliance and resistance through increased or decreased peak flows. By making appropriate adjustments on the ventilator you can lessen the chance for auto-PEEP and decrease work to trigger the ventilator.

Also facilitating recovery is our ***Predictive Learning Logic*** software which automatically anticipates the natural lung movement and works with the patient to decrease breathing effort and reduce stress. And working in any ventilator mode, our unique ***Bias Flow*** decreases ventilator response time and stabilizes baseline pressure.

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Weaning/Extubation Parameters

■ Respiratory Rate (RR) ■ Tidal Volume (TV) ■ Minute Volume (MV) ■ Slow Vital Capacity (SVC) ■ Maximum Voluntary Ventilation (MVV) ■ Negative Inspiratory Force (NIF)

For further information, call: 1-800-325-7472 (outside Missouri) 1-800-392-7318 (in Missouri)

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